Oracle Argus Safety

Japanese User's Guide

Release 7.0.3

E40571-01

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ORACLE

Oracle Argus Safety Japanese User's Guide, Release 7.0.3

E40571-01

Contents

Preface

This document describes the steps for using the components of the Argus Safety (Japanese) application.

Intended Audience

This document is intended for users of the Argus Safety Japanese (J) system.

Documentation Accessibility

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About This Book

This guide contains the following chapters:

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action such as Buttons, Dialog boxes, Check boxes, Combo boxes, Drop-down lists, Labels, Option (Radio) buttons, Tabs, Text boxes, etc.
"between quotation marks"	Information that may appear as-is on screen, or information provided by the user.
Note	Information that should be noted before proceeding with the instructions.
Important	Important information that must be noted to ensure accurate, reliable, or safe behavior of the system.
Tip	Information that enables easier completion of the current task or helps in completing other tasks.
Bold Underline	Link indicating that additional "pop-down" information is available.
ALL CAPITALS	Keyboard keys
Initial Capitals	Names of user interface elements, modules, applications, proper nouns, etc.

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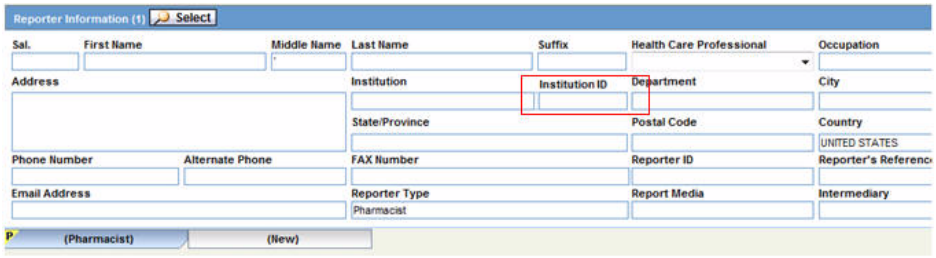
Case Form

This chapter lists the changes that have been introduced in Case Forms in the Argus Safety 7.0.3 release.

1.1 Reporter Information

- A new textbox field with name "Institution ID" has been added to Case Form > Reporter Information section for both English as well as Japanese users.

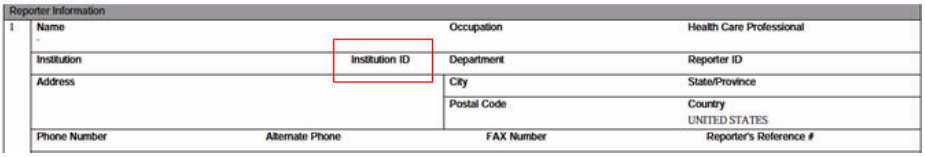
Figure 1–1 Case Form Report Information section - Sample Output



- The following are the attributes for this field:
  - Field Name (Unique Field Label): "Reporter Institution ID"
  - Field Form Label: "Institution ID"
  - Field Form Label (J)
  - Help Text:"Enter the Institution ID for the Reporter."
  - Help Text (J)
  - Hidden radio option set to "No". Hiding is allowed.
  - Read Only options are unchecked and disabled.
  - E2B Field and Research Field are unchecked by default.
  - Japanese IME Toolbar is disabled for this field in Case Form even for Japanese user.
  - Case Form Field Length: 15 AN. No validation required for alphanumeric data check.
- Both English and Japanese fields point to a common value.
- This field value is populated based on the Institution ID selected for the Reporter from the Reporter Lookup dialog.

- This field also allows manually entered / updated value directly in the Case Form irrespective of the value specified in the Institution field for the reporter. Manually entered Institution and institution ID field values are allowed in the Reporter Information section even if they are not specified / linked to each other as per Console Institution code list.
- As both the Institution or Institution ID fields can be present in Reporter Information, and if the user opens up Reporter Lookup for this reporter, then Reporter Lookup searches for reporters in Case or Console data based on the following logic:
  - Out of Institution and Institution ID fields first use Institution ID field with the rest of the search criteria fields. The Institution value is not used in this scenario on the Reporter Lookup search dialog.
  - If the Institution ID field is not specified in the Reporter Information or if it does not exist in the type-ahead values for this field on Reporter Lookup, then automatically remove the Institution ID field value in Reporter Lookup and search based on Institution field with rest of the search criteria fields.
  - If Institution field value also does not exist in the type-ahead values for this field on the Reporter Lookup, then remove the Institution field value as well in the Reporter Lookup and search based on rest of the search criteria fields.
  - If "Search all the reporters who belong to the institution found from the current search item" search option is also used, then it performs a search based on Institution ID or Institution Name - whichever is available on the Reporter Lookup dialog to identify the first set of reporters and subsequently use those reporters for second level search.
- This field is printed in Case Form Print for Reporter Information section as displayed for both English and Japanese users.

Figure 1–2 Case Form Report Information Print - Sample Output



- This field is audit-logged.
- This field is available under the following modules:
  - Case Listing Report
  - CIOMS II Line Listing Report
  - CDA Report
  - Advanced Conditions
  - Case Form Letter Placeholders as specified below:

    [reporter_inst_id:primary]

    [reporter_inst_id]:[n]

    [reporter_inst_id:selected]

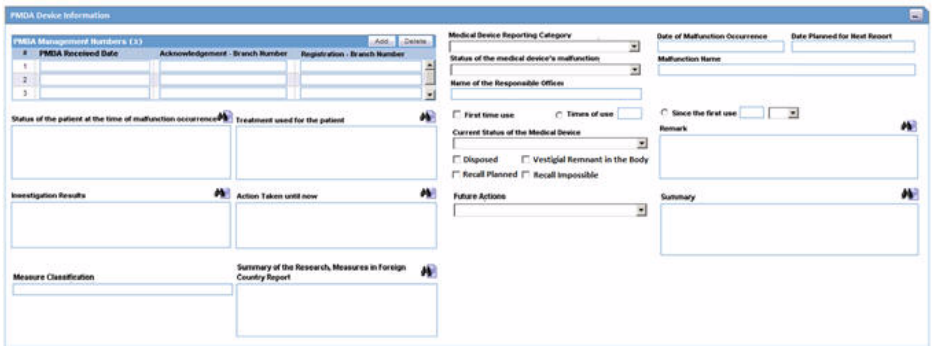
    [reporter_inst_id:corresp_contact]
  - Console Field Labels: Under ARGUS SAFETY > GENERAL > Reporter

- Console Field Validations: Under ARGUS SAFETY > GENERAL > Reporter

1.2 Products Tab

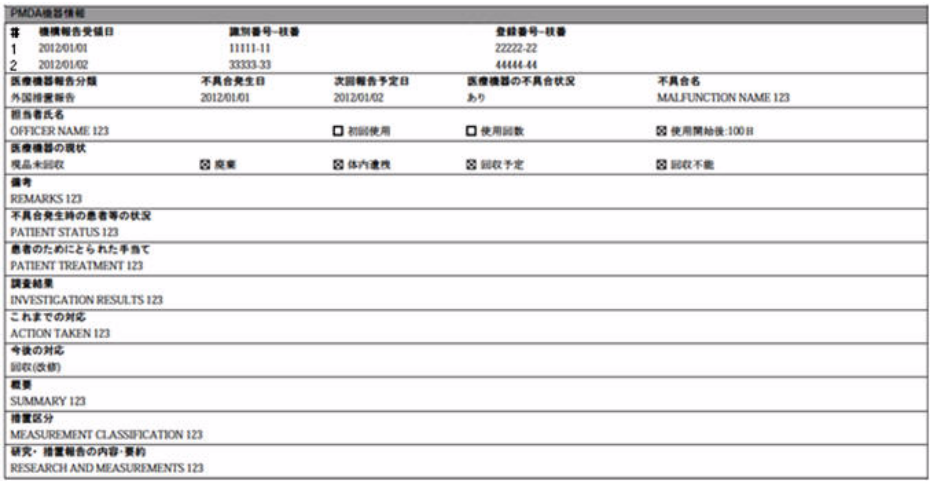
- A new standard section - "PMDA Device Information" has been added after "Device Information" section on Case Form > Products tab > Device sub tab.
- This section contains fields as specified in the screen mockup displayed below:

Figure 1–3 Case Form - PMDA Device Information section



- This case form section is available to all Argus J users on both English as well as Japanese views as uncollapsed by default only when Japanese module is enabled.
- It is displayed with Japanese labels on both English as well as Japanese views as this section is not meant for translation of data.
- The Modify, View and No Access rights to this section are based on the "Product Information (Device View)" option in Console > Access Management > Groups > Case Form section.
- Tabbing order of case form elements respects this new section in the order of UI elements as left to right and top to bottom.
- A new checkbox option - "PMDA Device Information" is available in Case Print - section selection dialog only to the Argus J user.
  - This checkbox is added right after "MedWatch Device Information" option in the Case Print options dialog. All the options after it are shifted further by one place.
  - This checkbox gets selected and unselected when user uses "Select All" and "Unselect All" options.
  - This checkbox remains unchecked by default and is disabled unless its parent section checkbox "Product Device Information" is checked by the user. If "Product Device Information" is unchecked later, then "PMDA Device Information" also gets unchecked and disabled. Case Form Print PDF report prints this section in Japanese after "MedWatch Device Information" section if it is selected for printing in the section selection dialog.

Figure 1–4 Case Form Print - PMDA Device Information Section



PMDA機器情報

#	機構報告受領日	識別番号-枝番	登録番号-枝番
1	2012/01/01	11111-11	22222-22
2	2012/01/02	33333-33	44444-44

医療機器報告分類	不具合発生日	次回報告予定日	医療機器の不具合状況	不具合名
外国措置報告	2012/01/01	2012/01/02	あり	MALFUNCTION NAME 123

担当者氏名				
OFFICER NAME 123		☐ 初回使用	☐ 使用回数	☒ 使用開始後:100日

医療機器の現状				
現品未回収	☒ 廃棄	☒ 体内遺残	☒ 回収予定	☒ 回収不能

備考
REMARKS 123

不具合発生時の患者等の状況
PATIENT STATUS 123

患者のためにとられた手当て
PATIENT TREATMENT 123

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INVESTIGATION RESULTS 123

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今後の対応
回収(改修)

概要
SUMMARY 123

措置区分
MEASUREMENT CLASSIFICATION 123

研究・措置報告の内容・要約
RESEARCH AND MEASUREMENTS 123

- A new checkbox option - "PMDA Device Information" is available in Case Copy - section selection dialog only to the Argus J user.
  - This checkbox is added right after "MedWatch Device Information" option in the Case Copy options dialog. All the options after it are shifted further by one place.
  - This checkbox is selected and unselected when the user uses the "Select All" and "Unselect All" options.
  - This checkbox is unchecked by default and is enabled for user selection.
  - The Case Form Copy function copies this section when a case is copied with this section checked in the Case Copy options dialog.
- All fields of this section are audit logged as other case form product device fields.
- All fields of this section are available under Console > System Configuration > Field Labels, Field Validations, and Advanced Conditions screens under the tree structure ARGUS SAFETY > PRODUCTS > PMDA Device. These fields are NOT required for Aggregate Reports.
- In Console ' System Configuration ' Field Labels screen, all these fields are available with the following attributes:
  - Hidden radio option set to "No". Hiding is allowed.
  - Read-Only options have been unchecked and disabled.
  - E2B Field and Research Field are unchecked by default.

1.3 Analysis Tab

- Up and Down buttons have been added to the PMDA tab.
- By default, the focus is on the first record. No action is performed when the user clicks on "Up" button when the focus is on the First record. If the focus is on any other record other than the first record, the system interchanges the position of the current record and previous record by clicking the "Up" button.
- No action can be performed when the user clicks on "Down" button when the focus is on the Last record. If the focus is on any other record other than the last

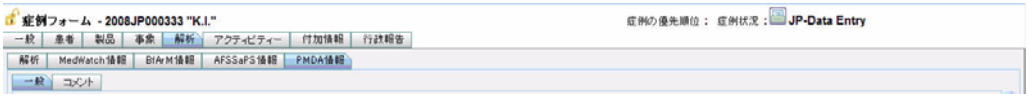
record, the system interchanges the position of the current record and next record by clicking the "Up" button.

- If there is no row in this section, then clicking on "Up" and "Down" buttons does not cause action.
- For existing customer data, the sort order value for existing records is populated as same as the order in which these were displayed to the user.
- The change in ordering of these product license rows in PMDA General tab is audit-logged.
- The product license ordering on the PMDA General sub-tab is also respected by the following:
  - PMDA Comments sub-tab > Product License dropdown
  - Case Form Print > PMDA General and Comments tab
  - PMDA E2B Report > Ordering of product dosages in DRUG section as per the logic specified below
  - PMDA Paper Report > Ordering of product dosages in DRUG section as per the logic specified below
- PMDA E2B and Paper Reports (Marketed Form 1-6 and Investigational Form 1-6) list the suspect products using the order of products specified in PMDA tab. Logic to be considered for PMDA E2B report is provided below, with the only change from the previous logic being for point b:
  - The company product for which the ICSR is scheduled is always listed first.
  - For the other company suspect Japanese products which are displayed on the PMDA tab, the order of products is considered from the PMDA tab.
  - The remaining suspect products (which are not listed on the PMDA tab).
  - Other concomitant products.
  - For each of the above categories (c), and (d), if there are multiple products, then the "Product details/First Dose" are used for the ordering of products. Earlier dates are before the later dates.
  - If there are multiple products with the same "Product details/First Dose" under any of the above category (c) and (d), then they are ordered using the product sort ID used in the case itself.
  - Within a product, if there are multiple dosage regimens, then they are ordered based on the dosage start dates.
  - If the date being used for ordering is null, then the product is put at the end in the same category.
  - For the Partial date, if the date is considered as 15th of the month, the month is considered as June of the year.

Figure 1–5 Case Form - PMDA tab

1.3.1 PMDA Information tab

The **PMDA Information** tab comprises two sub-tabs: **General** and **Comments**, as depicted in the following figure:



The details about the **General** and **Comments** sub-tabs are given in the following sub-sections:

- PMDA Information: General Tab
- PMDA Information: Comments Tab

1.3.1.1 PMDA Information: General Tab

The following figure depicts the **General** sub-tab of the **PMDA Information** tab:

The following table lists the fields in the **General** tab:

Table 1–1 Fields in the General tab

#	Field Name	Description
1	General	This represents the name of the sub-tab under PMDA tab.
2	Comment	This represents the name of the sub-tab under PMDA tab.
3	Japan first information Received Date (For Reporting)	This field represents the editable text box which displays the date the case was received by the Japanese pharma company (initial receipt date captured during case book-in). The format is **YYYYMMDD**. In case of a local case, this date represents the Case Initial Receipt date. In global case, this date is automatically populated by the date first opened by J user. The value is stored in the case when you perform direct/indirect **Save**. For example, **accept** from worklist stores the value indirectly.
4	Follow-up received date	This field represents the non-editable text box which displays the date the case follow-up information was received by the pharma company. If the follow-up is marked significant, the Japan Follow-up Received date is used as the reference date to schedule the reports. The format is **YYYYMMDD**.
5	Safety received date / or Central received date	This field represents the non-editable text box which displays the date the Safety group received the case. The format is **YYYYMMDD**.
6	Significant Changes	This is a non-editable checkbox to indicate whether the follow-up is significant or not. If the follow-up is significant, the Japan Follow-up date overrides the date used for report scheduling.
7	Japan follow-up received date	This field represents the editable text box which displays the date the case follow-up information is received by the pharma company. If the case is originated in some country other than Japan, this date represents the date first opened by the J user after the follow-up. If the follow-up is marked significant, the Japan follow-up received date is used as the reference date to schedule the reports. The format is **YYYYMMDD**. The time stamp of Case Open date done by first Japanese user after the latest foreign follow-up is automatically populated. The value is stored in the case when you perform direct/indirect **Save**. For example, **accept** from worklist stores the value indirectly.
8	Drug name and license number	The number of rows in this section is equal to the number of reports that need to be submitted to PMDA for this case. One report is scheduled for each of the Marketed License. One report each is scheduled for each Study License. The field is read only and show concatenation of Trade Name with License Number in brackets.
9	New Drug Category	This field represents the drop-down to select **License Category** LM to select value for **E2B J.8** item.

Table 1–1 (Cont.) Fields in the General tab

#	Field Name	Description
10	Japan Reporting type	This field indicates the Reporting Type. It is a drop-down list showing three possible values: Case Reporting, Research Reporting, and Action Taken.
11	Japan Reporting category	This field represents a drop-down List containing Reporting Category LM. This is a mandatory field for Argus J user. The selection of this field determines the report being created (ADR, Infection, Research, or Measures in foreign countries). The entries shown in this list are determined at run time by the values selected in items 9,10 and 12. When Reporting Category is not selected, the license does not create the report. The format of the value displayed in this drop-down is: [Reporting Category] - [Description]
12	Domestic Case / Foreign Case Clinical / Marketed	There are two fields which are non-editable text boxes. The first shows whether the case is foreign (if the country of incidence is not equal to Japan) or domestic (if the country of incidence is Japan). The second field shows the license type: **Investigational**, if the license on which the ICSR is based on is for an investigational drug, device, or vaccine. **Marketed**, if the license on which the ICSR is based on is for a marketed drug.
13	Completion Report (Case Complete)	This checkbox indicates the completion of the case report. A new **Case Complete** checkbox field is added to the **License** List box. This field is the driver for the E2b field J.6. A separate J.6 must be recorded for each ICSR. By default, this box is not checked.
14	PMDA Identification Number	The **PMDA Number** is displayed in the **PMDA** tab where all the ICSR licenses are displayed. This is the PMDA Acknowledgment Number given in Ack message item B.1.3. This number is used in J.4b from the first follow-up report.
15	Clinical Compound Number in the study of this case	This field is read only when the study is selected from the **Study** look up. When the study information is manually entered, **Clinical Compound Number** is editable. If there is no study information, the field is disabled.
16	Domestic	This field represents the Read-only text that is determined by the system.
17	Marketed	This field represents the Read-only text that is determined by the system.

1.3.1.1.1 Functionality Changes

The following are the functionality changes for the **PMDA Information > General** tab:

1. This tab is unique to Argus J module implemented system. It also displays the number of reports to be submitted for the case. Each row in the lower section represents a report. The number of reports to be submitted for a case is determined as per the following logic:

- General Rule
  - Reports are submitted for Marketed or Investigational licenses in Japan only for the suspect company products in the case.
  - All Japanese licenses (including hidden) listed in the event assessment are listed.
  - All suspected products with license and all Investigational licenses are listed in the **PMDA General** Tab.
  - Priority order of the Suspected product (Drug, Device, Vaccine) list is:

    Primary Suspected Product License

    Product entry order in the Case Form

    Marketed license, then Investigational
  - The license is displayed as the Trade Name and the License Number in parenthesis.

2. Japanese Receipt Date and Follow Up Dates table:

   It captures the Japanese received date label as **Japanese received** for each recorded follow-up in the **PMDA** tab. The system displays a list of all follow-ups that are entered in the **General** tab with the option to specify Japanese received for each follow-up entry.

   - When you change the **Japanese Received Date** from default, the justification pop-up with the message **Please enter the reason of information receipt date change** is displayed, wherein you are required to enter the reason of this date change.
   - When you change the **Japanese Receipt Date** or **Japanese Follow-Up Date**, if the changed date is older than the date in the **Information Receipt Date** of **General** tab, a pop-up window with the following error message is displayed:

     The date cannot be older than the first information receipt date of the case.
   - For the purpose of Report Scheduling in Japan, the **Japanese Aware Date** is used by checking the flag on **Use Japanese Aware Date for Reporting** as configured in the Reporting Destination Code List of Console. The Japanese Aware Date has the same behavior as the Standard Aware Date.

3. Reporting Category:

   The Reporting Category is a drop-down list with the values from Reporting Category Code List.

   - The Reporting category is a drop-down list with the values, as indicated in the table below. The drop-down content of the field depends on the previous selection in:
     - AE/Infection (in Infection check box in **Event** tab) - This is used only if all the events are AE, or all the events are **Infection**.
     - Domestic / Foreign (in Country of Incidence, **PMDA** tab, Dom = JP, Frgn <> JP)
     - License Type (Investigational or Marketed)
     - You can refer to the following table for the list of Reporting Categories in the drop-down list.

- The system clears the Japan Reporting Category if the dependent fields are modified after the selection has been updated.

Table 1–2 List of Reporting Categories

Category	Category Description	AE / Infection (in event tab)	Dom / Frgn	License Type
A	Domestic/Infection report (Marketed drug)	Infection	Dom	Mkt
B	Domestic/ADR report (Marketed drug)	AE	Dom	Mkt
C	Overseas/Infection report (Marketed drug)	Infection	Frgn	Mkt
D	Overseas/ADR report (Marketed drug)	AE	Frgn	Mkt
E	Research/Infection report (Marketed drug)	Infection	Any	Mkt
F	Research/ADR report (Marketed drug)	AE	Any	Mkt
G	Measures in foreign countries including	Any	Any	Mkt
H	Domestic/Infection report (Investigational drug)	Infection	Dom	Inv
I	Domestic/ADR report (Investigational drug)	AE	Dom	Inv
J	Overseas/Infection report (Investigational drug)	Infection	Frgn	Inv
K	Overseas/ADR report (Investigational drug)	AE	Frgn	Inv
L	Research/Infection report (Investigational drug)	Infection	Any	Inv

Table 1–2 (Cont.) List of Reporting Categories

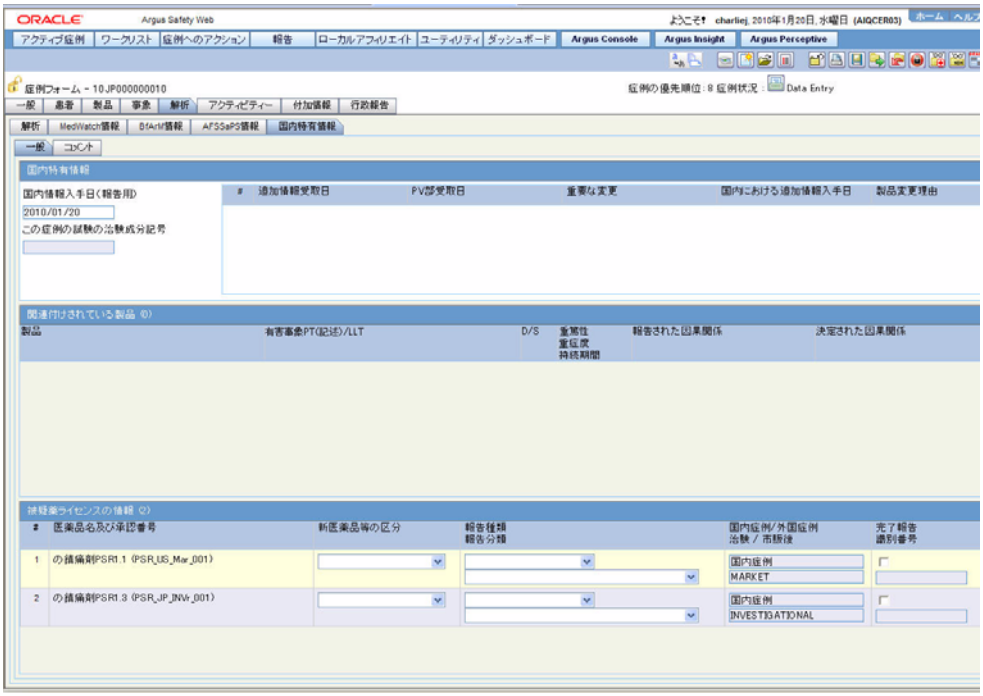
Category	Category Description	AE / Infection (in event tab)	Dom / Frgn	License Type
M	Research/ADR report (Investigational drug)	AE	Any	Inv
N	Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Investigational drug) such as production termination, product recall, product rejection, etc. (clinical study)	Any	Any	Inv
O	Research report (Quasi drug)	Any	Any	Any
P	Research report (Cosmetics)	Any	Any	Any

4. **PMDA** Tab > **General** > **Linked Product** section collects product in the Assessment table with the following rules:
   - System checks:
     - If the case is a foreign case
     - If the case has non-company product(s).
     - The non-company product(s) is/are marked as **Suspected**.
     - Under all above conditions, suspected company product in this case has equivalent Japanese license.
   - If there is non-company suspected drug in foreign cases, that product Trade Name and Generic name are used for matching with the Keywords from **Console J** > **Code List** > **Argus J** > **Reportable Product Keyword**.
   - This keyword is used for finding related company product family which needs reportability assessment when foreign case has non-company suspected drug. The keyword text is matched within either the **Product Name** or **Generic Name** fields of the Case Form. If entered keyword matches (partially or fully), the matching product family's Japanese license is assessed in the **PMDA** tab.
   - When there are multiple Japanese licenses in the matching family, all of these licenses are listed for assessment in the **PMDA** tab.
   - Products already existing in the Case form are not populated here.
   - In this section, the Causality Assessments are available.
   - Listedness is always **Unknown** for this section.
   - Hyperlinks are not available for this **Assessment** section.

Table 1–3 Field Descriptions

Field	Argus J User display
Product	Company product(s) using J Reportable Keyword are displayed.
Event PT (Description) / LLT	Event(s) in the case are displayed
D/S	D/S information is displayed as read-only
Seriousness	Event information is displayed as read-only
Severity	
Duration	
Reported Causality	Reported Causality type-ahead drop-down
Determined Causality	Determined Causality type-ahead drop-down

- You can assess the product for reportability in this table.
- This section's display status (Maximize/Minimize) is not dependent on a user preference:
  - This section is automatically minimized if there is no data.
  - This section is automatically maximized if there is data.



5. When you enter future date in **Initial Receipt Date** in **Case Form** > **General** tab > **General Information** > **Initial Receipt Date**, or **PMDA** Tab > **General** > **Initial Information Receipt** date, the application displays the following validation message:

   Receipt Date cannot be a future date

6. Product Change Justification:

- When you click the **OK** button (the button appears in each follow-up row of **Product Change Justification** column in the follow-up info table), the Justification Table pop-up is displayed to view update information.
- The button is enabled only when Product Change justification exists for the case.

  For example, Scenario # 1 - it only asks for justification if there is a submitted report against the product which is subject to deletion and you unlock the case with follow-up to delete that product.

  Scenario # 2 - In addition, when you create a company product:

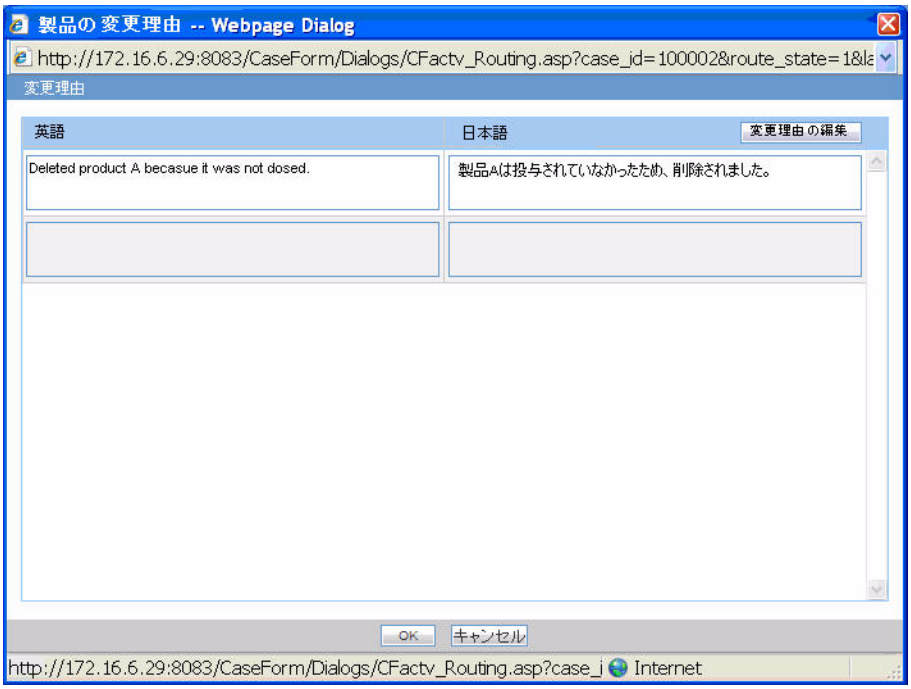
  – Schedule an Expedited report against the company product.

  – Get that report to **Submitted** status.

  – Unlock case a, add follow-up and change the company product to a different company product (change justification is displayed).

  – Enter something and navigate to **PMDA** tab.

  – The button is enabled.



- The Justification list populates all the product justifications entered for the follow up.
- The Translation justification is editable using the following steps:

  – Select the justification from the list. This highlights the row.

  – Click the **Editing the justification** button.

    This opens Justification pop-up and you can edit the justification.

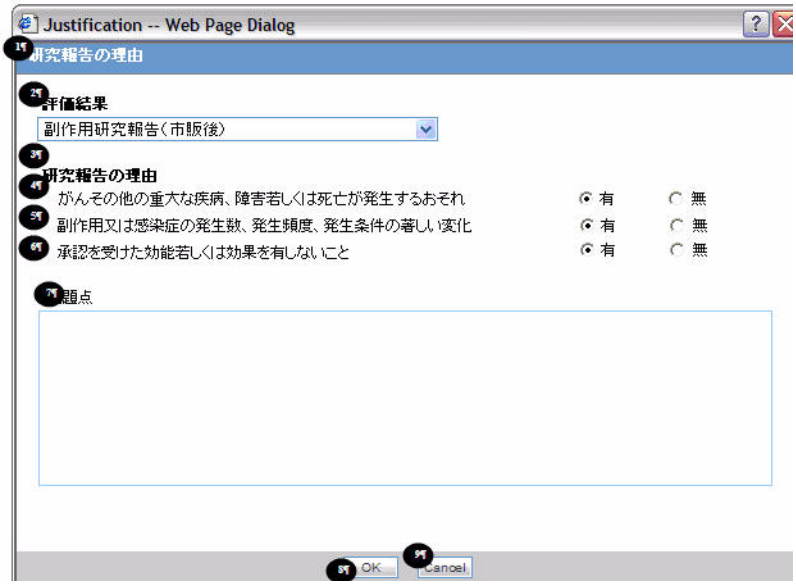
7. When you select the Research Report Type Reporting category, a pop-up **Reason for subject of the Research Report** is displayed to enter the reason of the Research report.

- The pop-up UI section opens only when any one of the suspected drug license table has one of following Reporting Category selected:

Table 1–4 Reporting Categories

#	Reporting Category (English meaning)
5	Research/Infection report (Marketed drug)
6	Research/ADR report (Marketed drug)
12	Research/Infection report (Investigational drug)
13	Research/ADR report (Investigational drug)
15	Research report (Quasi drug)
16	Research report (Cosmetics)

- The information is multiply stored when multiple suspected licenses with the Research Reporting Category exist. Each Research Reporting Category has a circle in Green color symbol after the justification is entered in the pop-up window.
- Justification pop-up
  - User Interface:



The following table explains the fields used in the **Justification** dialog box:

#	Field Label Value	English Label Name	Purpose	Field Length	Audit Log
1	N/A	Reason of Research Report	Title of the UI	N/A	N/A
2	N/A	Assessment Result	Read Only	N/A	N/A
3.	N/A	Reason of Research Report	Title of the section	N/A	N/A

#	Field Label Value	English Label Name	Purpose	Field Length	Audit Log
4.	Reason for subject of the Research Report - Possibility of occurrence of serious disease such as cancer, disorder, or death	Possibility of occurrence of serious disease such as cancer, disorder, or death	Radio button Yes - exists No - does not exist	N/A	Yes
5.	Reason for subject of the Research Report - Significant change on event or infection occurrence number, frequency, and condition	Significant change on event or infection occurrence number, frequency, and condition.	Radio button Yes - exists No - does not exist	N/A	Yes
6.	Reason for subject of the Research Report - It doesn't have acknowledged effectiveness	It doesn't have acknowledged effectiveness	Radio button Yes - exists No - does not exist	N/A	Yes
7.	Reason for subject of the Research Report - Problems	Problems	Text Field, 20,000 field length.	20,000	Yes
8.	N/A	OK	Button	N/A	N/A
9.	N/A	Cancel	Button	N/A	N/A

Items # 4, 5, and 6 have radio buttons **Yes** and **No** to store the answer.

Field #2, **Assessment Result**, is a read-only field to show either the value from Literature Intake Assessment or the Reporting Category selected in the **PMDA General** tab. The following table illustrates the drop-down content based on the Reporting Category:

#	Drop-down Content (English meaning)	Reporting Category
1	Not Necessary	
2	AE Case	A, B, C, D, H, I, J, K
3	Research/Infection report (Marketed drug)	E
4	Research/ADR report (Marketed drug)	F
5	Research/Infection report (Investigational drug)	L
6	Research/ADR report (Investigational drug)	M
7	Research report (Quasi drug)	O

#	Drop-down Content (English meaning)	Reporting Category
8	Research report (Cosmetics)	P
9	Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Marketed drug)	G
10	Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Investigational drug)	N

- The **Problems** section text field stores text information.
- At least one **Yes** radio button has to be filled in the User Interface, and if this condition suffice, the UI can be closed. If this is not fulfilled, a message:

  At least one question has "Yes" selected is displayed to suffice the condition.
- This is not printed in the Case Form Print.
- Once you select **Research Reporting Category** and enters the reason, and then re-selects the Reporting Category to Non-Research Reporting Category, the system displays a warning message:

  Trying to select non-Research Reporting Category. If changed, the already entered "Reason of the Research Report" will be removed. Continue? is displayed.

  If you select **OK**, the reason is deleted. If **Cancel** is selected, the Reporting Category change is aborted.

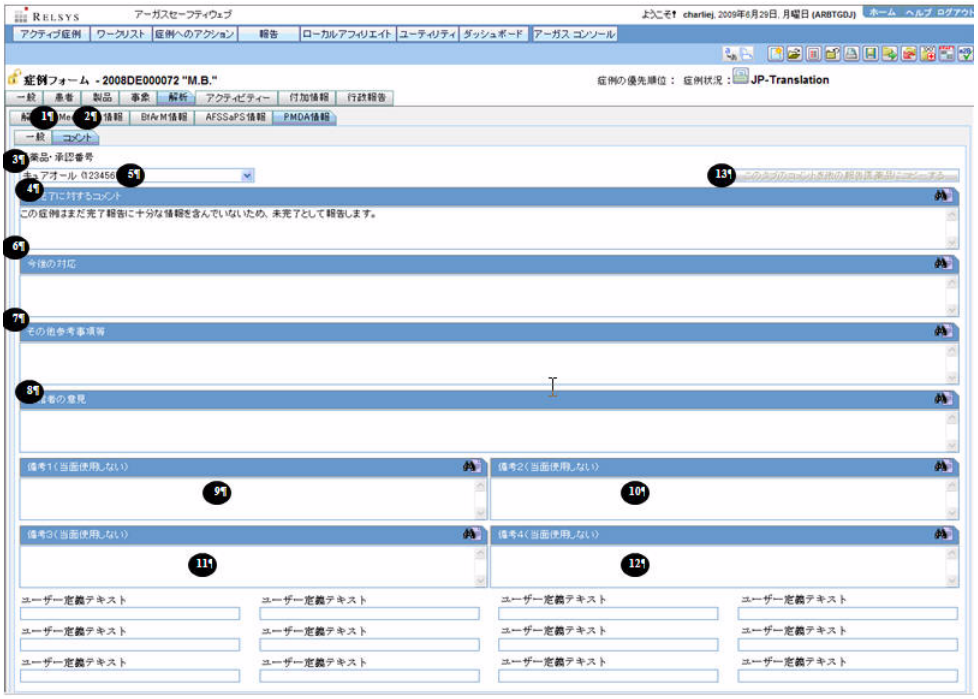
8. In case of a foreign case, if you select **Under clinical trial for partial change (clinical study for change on indication/listedness)** in the License Category drop-down in the **PMDA General** tab, the system automatically displays pop-up window with following message:

   Under clinical trial for partial change (clinical study for change on indication/listedness)" has been selected, so "TIKEN" needs to be entered in the "Caseform/Product/Note.

   - The pop-up UI has **OK** button only.
   - This pop-up is displayed every time this License Category is selected.
9. Each section has the **Minimize** button to hold the sections. The **Associated Product Assessment** section is minimized when the product does not exist.

1.3.1.2 PMDA Information: Comments Tab

The following figure depicts the **Comments** sub-tab of the **PMDA Information** tab:



The following table lists the fields in the **Comments** tab:

Table 1–5 Fields in the Comments tab

#	Field Name	Description
1	General	This represents the Sub-tab of the **PMDA Information** tab.
2	Comment	This represents the Sub-tab of the **PMDA Information** tab.
3	Product, License No	This is a drop-down field. It allows you to enter J specific narrative information based on the each suspected drug license.
4	Comment on incomplete	This field is unique to Japan. This field is an editable text that maps to DTD element J.7 as per PMDA. In case of an incomplete report, input a comment in **J.7** <mhlwadmicsrcommentsincomplete> for the report being incomplete.
5	E.g. Cure_All MKT (xxxxxxxxxxxxxxx)	This field represents the E.g. Sample License for which the narratives are being written. All the narratives written in the various text boxes are applicable to this License.
6	Counter measure for the future	This field is unique to Japan. This field is an editable text that maps to the **J.9<mhlwadmicsrcountermeasures>** DTD element as per PMDA. The company inputs the counter measures for the future based on the evaluation made by the reporting company on the concerned adverse effect infection, etc. For foreign case, the company inputs the counter measures taken by the Japanese reporting company, and not the foreign company. The field size is 10000J.
7	Other references	This field is unique to Japan. This field is an editable text that maps to the **J.10<mhlwadmicsrreporttimesevent.>** DTD element as per PMDA.

Table 1–5 (Cont.) Fields in the Comments tab

#	Field Name	Description
8	Comment of sender	This field is unique to Japan. This field is an editable text. This refers to the **B.5.4 < sendercomment >** element.
9	Remarks 1	This field is unique to Japan. This field is an editable text that maps to the **J.13.1** DTD element as per PMDA. The DTD element name is: <mhlwadmicsrremarks1>
10	Remarks 2	This field is unique to Japan. This field is an editable text that maps to the **J.13.2** DTD element as per PMDA. The DTD element name is: <mhlwadmicsrremarks2>
11	Remarks 3	This field is unique to Japan. This field is an editable text that maps to the **J.13.3** DTD element as per PMDA. The DTD element name is: <mhlwadmicsrremarks3>
12	Remarks 4	This field is unique to Japan. This field is an editable text that maps to the **J.13.4** DTD element as per PMDA. The DTD element name is: <mhlwadmicsrremarks4>
13	Copy the comments in this tab to other reporting licenses	This button copies all the comments in the UI to other licenses in the list. When there is only one product, the button is disabled.

1.3.1.2.1 Functionality Changes

The following are the functionality changes for the **Comments** tab:

1. This tab captures narratives data for various J DTD elements that are reported in E2B reports being submitted to PMDA.

   For details, refer to the DTD Mapping document.

2. **Product, License** drop-down contains the same suspected drug licenses listed in the **PMDA General** tab. This is to include distinct narratives for each license. Each comment is applied to the selected License Number within the drop-down field. So a unique narrative field is available for each license. In the **Product, License** drop-down, licenses are displayed in the following format:

   Trade Name (License number)

   Depending on which license is picked, appropriate Narrative fields is displayed.

3. When **Copy the comments in this tab to other reporting licenses** is clicked, a message **Comments already exist for other licenses and will be overwritten. Do you wish to continue?** is displayed. If you click **OK**, the copy process is continued, and if you click **Cancel**, the copy is canceled.

4. This tab has auto text generation functions on each text box:

   - UI: (buttons are located on the right side of each binocular icon).
   - The label of the button **Generate**
   - The function of the button is the same as **Generate** buttons in the **Analysis** tab. The PMDA tab does not have English or other languages equivalent fields,

therefore, the auto narrative functions populate the texts by using Japanese Narrative template of the Console Configuration.

1.3.2 Product License Value

- The Product License display value on PMDA tab has been changed at the following places:
  - PMDA General tab > Product Licenses section ' Product License column
  - PMDA Comments tab > Product License dropdown field
- The following display value format is used at these places for product license values:

  <Case Form Product Tab Name (J)><space><#[x]><space>(<License Trade Name (J)>)<space>(<License Type><space>-<space><License Number>)

  Where

  <Case Form Product Tab Name (J)><space><#[x]>: is the same text that is displayed as Product tab name for the product to Argus J user. "<space><#[x]>" is present only if the tab name is same for multiple products either due to multiple study drug under same study or due to non-study multiple products with same name.

  <License Trade Name (J)>: is the Trade Name (J) from Console license configuration for the license of the product.

  <License Type>: is printed as "Inv" or "Mkt" base on whether the License Type is Investigational or Marketed.

  <License Number>: is the License Number from Console license configuration for the product license.

1.3.3 PMDA Event Reportability Updates

- The following field values from the PMDA Event Reportability Print section are available/stored in database tables/columns so that they can also be queried for other custom reporting needs:
  - Reportability Status - Reportable, NUPR Reportable, Not-Reportable
  - Reportability Timeframe value in days
- To avoid unwanted performance impact on Case Save action, these field values should not be calculated on each case save. These are calculated based on only the following actions:
  - Manual method - "Recalculate PMDA Event Reportability" button

    A new button "Recalculate PMDA Reportability" has been added to Case Form > Analysis > PMDA Info > General tab > Product License section header bar right before the "Up" and "Down" buttons.

    Clicking on this button triggers the fresh calculation of the PMDA Event Reportability data.

    This button is not displayed when the user opens a previous case revision in the Case Form.
  - Automatic method - Case Lock action

A new common profile switch has been added in Console > System Configuration > System Management > Argus J > Reporting as described below:

Key Label: Perform PMDA Event Reportability calculation on each Case Lock

Key Type: Radio Options

Key Options: "Yes" and "No"

Default Value: "No"

If this common profile switch is set to "Yes", then when the case is locked from any point in Argus Safety application, it triggers the fresh calculation of the PMDA Event Reportability data.

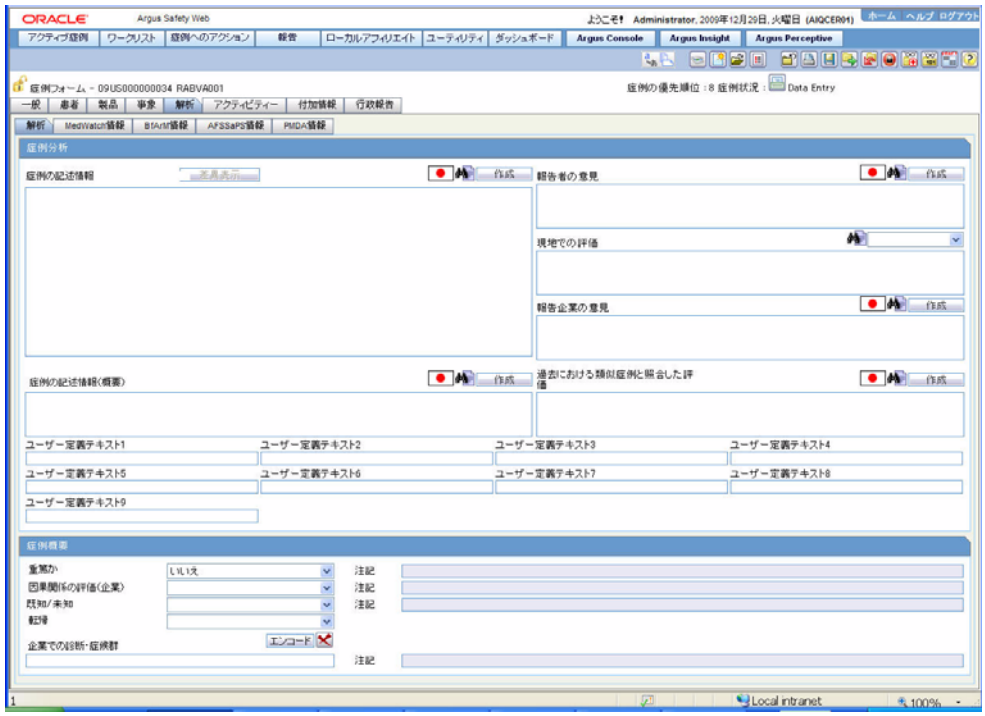
- The following is implemented during the PMDA Event Reportability calculation process:
  - While these values are being calculated by application, a standard processing icon is displayed on the case form.
  - If any unsaved changes are done by the user in the case data before clicking this button, then all those changes are considered and saved during the calculation process.
  - Once the calculations have been completed, the calculated values are saved in the appropriate database tables, along with the case revision data.
  - After successful completion, a standard Argus Safety message box is displayed with OK button and message - "PMDA Event Reportability data has been successfully calculated and saved with the case data for the current case revision." This is applicable only for "Recalculate PMDA Event Reportability" button click and not for Case Lock action.
- For the latest case revision, these field values are available in regular Argus Safety database case form tables.
- For previous case revisions, the field values are available in the DLP database case form history data tables.
- For the case revisions, for which PMDA Event Reportability data is not calculated, it is carried-over from its previous case revision for the case form / DLP database tables as well as for displaying it in the Case Print.
- Case Form Print > PMDA Event Reportability section > Reportability column > Reportability Status and Timeframe value is calculated / printed based on the reporting rules that existed at the calculation point.
- Other fields which are displayed as part of Case Form Print > PMDA Event Reportability section for each case revision are not required to be saved in database tables, but are calculated / printed along with the reportability fields in the Print PDF for that case revision.
- Following field values in Case Form Print > PMDA Event Reportability section are also calculated / printed based on the Console configurations that existed at the calculation point.
  - Outline of Clinical Trials (J.12 section)
  - Listedness As per Datasheet (based on the active datasheet as that point)
- The following note is printed at the bottom of PMDA Event Reportability section print - "# PMDA Event Reportability last calculated on case revision # <XXX> at <YYYY/MM/DD HH:mm:ss> JST", where:

  - <XXX> is the case revision number as displayed in case revisions dialog for which the PMDA reportability was calculated.
  - at <YYYY/MM/DD HH:mm:ss> is the time when it was last calculated as per the Japan standard time. It is calculated based in the common profile switch Argus J > Reporting > "Offset from GMT used to calculate Japanese date/time fields (in hours)"

- For existing/migrated cases, the data displayed as part of Case Form Print > PMDA Event Reportability section will not be available for previous or latest case revisions. It will be created going forward as those cases are saved by users in Argus Safety application.
- No audit log is required for these values calculated and stored in database as these as internally calculated values and no updates are allowed from any user interface.
- This PMDA Reportability data is not copied during Case Copy action.
- While calculating the earliest timeframe value for PMDA Event Reportability section, existing application logic considers only those matching reporting rules for which the reporting destination is configured as below to identify if it is a PMDA or non-PMDA reporting rule:
  - Reporting Destination > Agency Type field is specified as Regulatory Authority and
  - Reporting Destination > Agency Country field is specified as Japan.

1.3.4 Case Form - PMDA Analysis tab

The Case Form for the PMDA Analysis tab comprises the **Case Analysis** tab, the **BfArM Information** tab, the **MedWatch Device Information** tab, the **AFSSaPS Info** tab, and the **PMDA Information** tab, as depicted in the following figure:



1.3.5 PMDA E2B Report Mapping Updates

- PMDA profile E2B transmission logic for SERIOUSNESS [A.1.5.2] tags considers those events which have been included in the PMDA E2B based on event reportability criteria. This is applicable to the following tags:
  - SERIOUSNESSDEATH
  - SERIOUSNESSLIFETHREATENING
  - SERIOUSNESSHOSPITALIZATION
  - SERIOUSNESSDISABLING
  - SERIOUSNESSCONGENITALANOMALI
  - SERIOUSNESSOTHER
- E2B transmission logic for SERIOUSNESSDEATH tag which currently looks at death details even though it is not related to any event included in the E2B has been removed. It is transmitted as 1 (Yes), only if at least one event which is included the E2B report has Death associated with it. Otherwise, it is transmitted as 2. This is applicable to all E2B profiles - ICH, FDA, EMEA and PMDA.
- DRUGSTARTDATEFORMAT and DRUGSTARTDATE (B.4.k.12a and b): PMDA profile E2B transmission logic is also corrected to consider only the reportable events (which are included in the E2B report) when applying the following existing rule:

  When a case has REACTIONSTARTDATEFORMAT and REACTIONSTARTDATE (B.2.i.4a and b) earlier than the first suspect drug's DRUGSTARTDATEFORMAT and DRUGSTARTDATE (B.4.k.12a and b), then the system does not transmit the first suspect drug's B.4.k.12a and b for PMDA reports. When there are multiple events, the comparison is executed in between the oldest REACTIONSTARTDATE, and DRUGSTARTDATE. If there are partial dates, the date are considered as 15th of the month, and the month is considered as June of the year. (The first suspect drug here means the drug for which the report has been scheduled).
- All the E2B check validations for all profiles - ICH, FDA, EMEA and PMDA, related to the following tags have been corrected to refer to only the seriousness of the events which are included in the E2B report:
  - SERIOUS
  - SERIOUSNESSDEATH
  - REACTIONOUTCOME
- For PMDA E2B reports, if there are no reportable events for the E2B / PMDA Paper Reports, then instead of opening PMDA ICSR Validation Report with missing mandatory tag errors for REACTIONMEDDRAPT and REACTIONMEDDRALLT tags, the application displays an Argus standard messagebox with OK button and error message - 'No reportable event exists for the report'.
  - This logic is applicable for PMDA Reporting Catergories A,B, C, D, H, I, J, K only.
  - This logic is not applicable to downgrade or nullification reports.
  - This message is displayed in all scenarios wherever the application attempts to open PMDA ICSR Validation Report directly or indirectly, including but not limited to, the following scenarios:

User attempts to open PMDA E2B report in E2B Viewer

User attempts to open PMDA ICSR Validation Report

User attempt to import follow-up E2B and the application is attempting to open PMDA ICSR Validation Report because the E2B being created for the target case does not have any reporting event.

1.4 Additional Information Tab

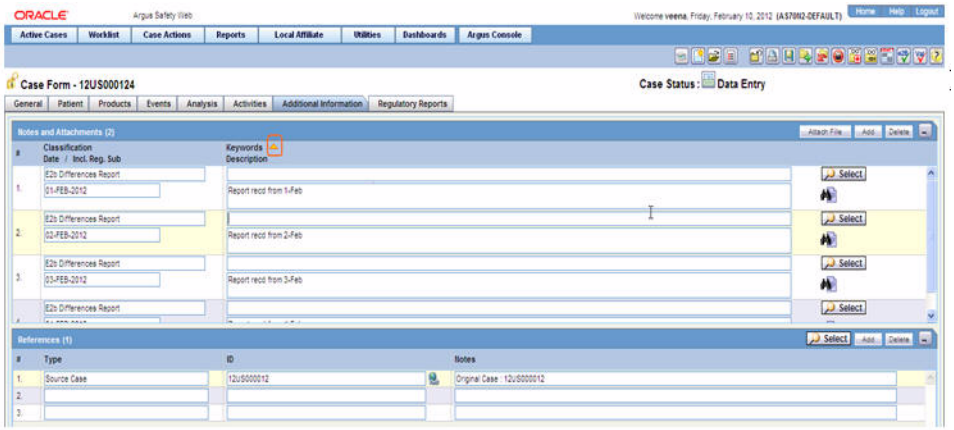
- Notes and Attachment section of Additional Info tab has been updated with an option to sort on the column headers (similar to Activities tab 'Action Items sorting feature) to sort the records based on the fields in Notes and Attachment section:

Field	Description
#	By default, "Upward Arrow" is displayed on the column header "#" System displays the records in the ascending order of the sequence in which the records are entered. On clicking the column header "#" for the first time, records are sorted in the descending order (numerically) of the Sequence number and "Downward Arrow" are displayed next to "#" column header. On clicking the column header "#" for the second time, records are sorted in the descending order (numerically) of the Sequence number and "Upward Arrow" are displayed next to "#" column header. On subsequent clicks to "#" column header, system toggles between "Downward Arrow" and " Upward Arrow " and its corresponding toggle functionality.
Classification	On clicking this column header for the first time, records are sorted in the ascending order (alphabetically) of the Classification and an "Upward Arrow" is displayed next to the "Classification" column. On clicking this column header for the second time, records are sorted in the descending order (alphabetically) of the Classification and a "Downward Arrow" is displayed next to the "Classification" column header.n header. On subsequent clicks to the "Classification" column header, the system toggles between "Upward Arrow" and "Downward Arrow" and its corresponding toggle functionality.
Keywords	On clicking this column header for the first time, records are sorted in the ascending order (alphabetically) of the "Keywords" and an "Upward Arrow" is displayed next to the "Keywords" column header. On clicking this column header for the second time, records are sorted in the descending order (alphabetically) of the "Keywords" and a "Downward Arrow" is displayed next to the "Keywords" column header. On subsequent clicks to the "Keywords" column header, the system toggles between the "Upward Arrow" and "Downward Arrow" and its corresponding toggle functionality.

Field	Description
Date	On clicking this column header for the first time, records are sorted in the ascending order (chronologically) of the "Date" and an "Upward Arrow" is displayed next to the "Date" column header. On clicking this column header for the second time, records are sorted in the descending order (chronologically) of the "Date" and "Downward Arrow" is displayed next to the "Date" column header. On subsequent clicks to the "Date" column header, the system toggles between "Upward Arrow" and "Downward Arrow" and its corresponding toggle functionality.
Description	On clicking this column header for the first time, records are sorted in the ascending order (alphabetically) of the "Description" and an "Upward Arrow" is displayed next to the "Description" column header. On clicking this column header for the second time, records are sorted in the descending order (alphabetically) of the "Description" and a "Downward Arrow" is displayed next to the "Description" column header. On subsequent clicks to the "Description" column header, the system toggles between the "Upward Arrow" and "Downward Arrow" and its corresponding toggle functionality.

- Sorting is remembered only till the time when the case is kept open.
- After the records in Notes and Attachments are sorted, if the following options are invoked without closing the case, the sort order is respected in these modules (similar to Activities 'Action Items sorting feature):
  - Case Form Print
  - Medical Review
  - Copied Case

Figure 1–6 Case Form - Additional Information tab



2

Case Actions

This chapter lists the changes that have been introduced in Case Actions in the Argus Safety 7.0.3 release.

2.1 PMDA Event Reportability

1. "PMDA Event Reportability" has been added to the "Print Case" dialog which opens up from Case Actions > Print > Case Form (Ctrl+Alt+P) in the location specified in the mockup screen below.
   - This option is displayed only for Argus J users.
   - This option is enabled for the Users belonging to at least one User Group having Modify/View access to Console > Access Management > Groups > Case Form > Case Analysis-PMDA option.
   - "Select All" and "Deselect All" buttons update the checkbox for this section as well.
2. On marking this option in Print Case dialog, the "PMDA Event Reportability" section is printed in the Case Form report after PMDA Comments section.
3. All the fields of the PMDA Event Reportability section in Case Form Report print data as per the version of the case opened.

4. A green dot symbol is displayed right after the Reporting Category dropdown value in Case Form ' PMDA Comments sub tab for each product license as soon as a reporting category is selected for that product license.

   - Research Reporting Category:

     If the user selects a Reseach Reporting Category (E, F, L, M, O and P), then the application retains the existing functionality of automatically opening the existing Research Reporting Category Justification dialog.

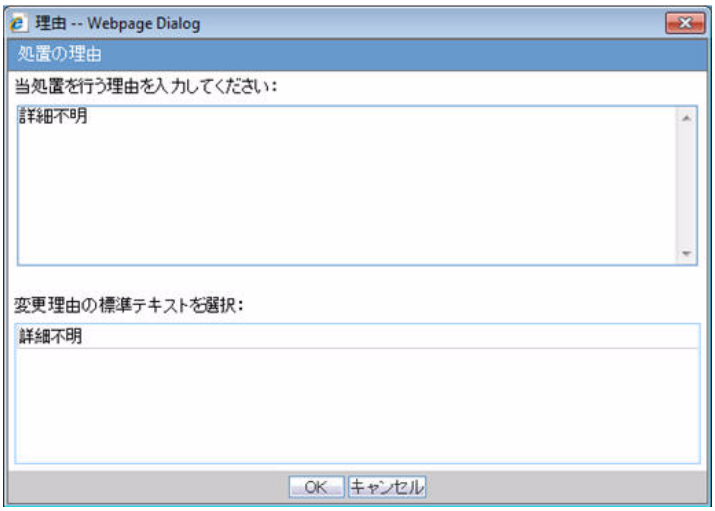
     All existing functionality related to Research Reporting Category Justification dialog is retained as is.

   - Other Reporting Category:

     If the user selects any other Reporting Category, then the standard Justification dialog opens up automatically.

     Manual clicking on the green dot symbol also opens up the standard Justification dialog to capture the final assessment text in Japanese for that product license as displayed below.

Figure 2–1 Case Form - Reporting Category Justification dialog



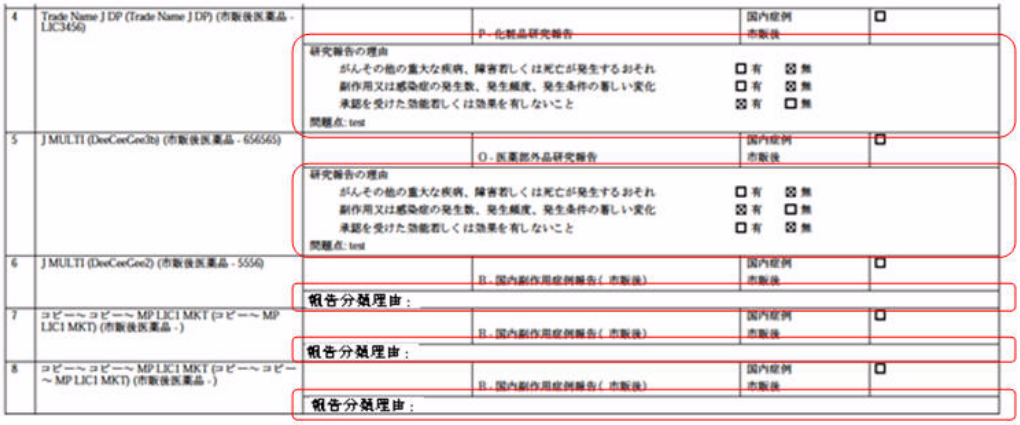
The dialog displays the list of pre-configured justification text from Justification code list for this field. By default, "Not Specified" is available in Justification code list for this field.

The justification dialog is displayed in Japanese to capture final assessment text in Japanese with max length of 20000 characters.

The title of this justification dialog is displayed as "Assessment Justification".

The justification text is optional and the green dot is always displayed for non-research reporting categories even if no justification text is specified so that user can click on it and provide it at any point of time later.

- Data fields from Justification dialogs for both research as well as non-research categories are printed in Case Form Print along with PMDA General tab > Product License section as shown below:



5. The PMDA section contains the following columns:

- Reporting Category:

  This column prints the list of distinct Reporting Categories for the Japanese Product License as selected in PMDA tab in an alphabetical order.

  Reporting Categories which are not mentioned in PMDA-General tab are not printed in PMDA Event Reportability section.

- Product License:

  This column prints the Japanese Product Licenses as listed in the PMDA General tab against the associated reporting categories listed in the first column in the same order, as listed in the PMDA General tab.

  The product licenses which do not have a reporting category assigned to them are not listed in this section.

- Assessment Reason:

  This is printed at Product License level at the end of all the event rows.

  It is printed in the format - "????: <Value>".

  The value is printed as specified on Case Form > PMDA Comments sub tab > Product License section > Reporting Category > Research Reporting Justification dialog > "Reason for subject of the Research Report - Problems" for research reporting categories (E, F, L, M, O and P) and regular Justification dialog for all other reporting categories. for the current product license.

  If no value is available to print, then only header text is printed.

- Outline of Clinical Trials:

  This is printed at Product License level at the end of all the event rows.

  This is printed only for Investigational Reporting categories (H, I, J, K, L, M and N). It is left blank for other reporting categories as this information is not printed in PMDA Expedited Reports for other reporting categories.

  It is printed based on data from all the studies configured in Console with matching clinical compound number as for the current product license configuration.

  Latest study configuration data from Console would be used to print these fields for the case revision data being printed.

  It is printed in following format:

- Event (PT/LLT)

  This column prints all the events entered in the case in the format: <Description as reported in Japanese (Event PT (J) / LLT (J))> as displayed on the screen mockup below.

  If description as reported in Japanese is missing, then the following is printed in the Event column:

  <Desc. as reported in English>

  All these events are repeated against all the product licenses, listed in the same order as in the Case Form > Event Assessment tab

  An Asterisk(*) is printed in this column for the events that are marked as "Do not include in Reports" in the below format:

  <Description as reported in J> (PT (J) / LLT (J))*

  A footnote "Event that are excluded from reportability" is printed at the end of Event Reportability section of Case Form Report if the case has events marked with "Do not include in Reports" in the Case Form Events tab.

  The text "No MedDRA Term" is printed for events which are not encoded in the below format:

  <Description as reported (No MedDRA Term)>

- Seriousness

  If the Event is "Fatal", then '"F" is printed against the Event.

  Else if the Event is "Life Threatening", then "LT" is printed against the Event.

  Else if the Event is neither "Fatal" nor "Life threatening", but has any other Seriousness criteria marked, '"S" is printed against the Event.

  Else "NS" is printed against the Event.

  However, if the Event is neither "Fatal" nor "Life threatening" and the Console Common Profile Switch under Argus J > E2B > "Seriousness criteria in Event Reportability Matrix" is configured to "Case Level Seriousness", then the value for this column is printed same for all events based on Case Form > Analysis tab > Case Seriousness field.

- Listedness

  This column prints the Listedness of the event as per datasheet followed by listedness as determined in the case. It is assessed against the same datasheet version that is used in Case Form Event Assessment tab.

  This column prints 'Unlisted' for Unlisted events and 'Listed' for Listed events as per the listedness specified in Case Form Event Assessment tab.

  This column prints 'Unknown for events with Listedness set to 'Unknown'.

  This column prints 'Data not entered' for events without listedness entered.

  While determining the listedness as per datasheet, only latest datasheet from Console would be executed against the case revision data being printed.

- Causality (As Reported / As Determined)

  This column prints the Causality As reported followed by causality as determined.

This column prints the causality terms in Japanese as per the Event Assessment tab for "As Reported", and "As Determined".

This column prints 'Data not entered' for events without relatedness entered.

- Listedness Justification

  If Listedness Justification (J) is available for the Product License - Event, then it is printed in a row below Seriousness, Listedness, and Causality columns.

  If Listedness Justification (J) is not available, then Listedness Justification entered in English is printed.

  Otherwise, Listedness Justification row is not printed.

  This value is printed in the format as below:

  <Justification Value>

- Causality Justification

  If Causality Justification (J) is available for the Product - Event, then it is printed in a row below Seriousness, Listedness, Causality columns.

  Otherwise, If Causality justification (J) is not available, then Causality justification entered in English is printed.

  Otherwise Causality justification row is not printed.

  This value is printed in the format as below:

  <Justification Value>

  If both Listedness Justification and Causality Justification are available, then these are printed in the same row but in separate lines.

- Reportability

  This column prints 'Reportable' or 'Non-Reportable' based on the final reportability of the event as per the existing logic in the Event Reportability matrix.

  For reporting category A and B only, if the event is not reportable as per PMDA Event Reportability matrix criteria then it is assessed if it is reportable for Non-Serious Unlisted Periodic Report (PSR Form 7-2) as per the following criteria. If it is reportable in PSR Form 7-2, then 'NUPR Reportable' is printed, Otherwsise, 'Non-Reportable' is printed.

  Event is not serious as per Case Form Events tab

  Event is related (either of As Reported or As Determined Casuality is reportable) for the current product as per Case Form Event Assessment tab.

  Event is unlisted for the current product license as per Case Form Event Assessment tab

  Event is not marked as Infection event as per Case Form Events tab

  For all the events which are "Reportable", the same cell also prints the event reporting timeframe for which this event qualifies to be reported.

  This value is printed right under the "Reportable" text in format - "(<xx>?)" e.g. "(15?)" (15 days)

  This value is derived for each event based on the report scheduling rules configured in Console for the current license and current reporting category. The shortest timeframe from the matching rule is printed.

Latest reporting rules from Console would be executed against the case revision data being printed.

As reporting rules are executed against the case data in the database, hence any unsaved changes in the case would not be accounted while matching the reporting rules.

If no matching rules are found, then nothing is printed for event reporting timeframe.

6. If the Product, Event or Justification data do not fit in their respective columns, the text wraps within its own cell of the table.
7. This information as displayed below is printed below a header row with section label:

   "PMDA Event Reportability" (similar to header row for other case form section).
8. If no data is present for this section then, it prints "No information present" in the header row itself (same as for other case form sections).

Figure 2–2 Case Form - PMDA Event Reportability section of Case Form Report

Reporting Category	Product License	Event (PT / LLT)	Seriousness	Listedness (As per Datasheet / As per Case	Causality (As Reported / As Determined	Reportability
B	Tylenol (Lic1000)	Fatty acid deficient (Fatty acid deficiency / Fatty acid deficiency)	F	Listed / Unlisted	Not Related / Probable	Reportable (15 day)
			Listedness Justification: Not Specified Relatedness Justification: Not Specified			
		Red Eyes(Ocular hyperaemia / Red Eye)	S	Listed / Listed	Not Related / Not Related	Not-Reportable
		Fever (No MedDRA Term)	LT	Unlisted / Unlisted	Not Related / Not Related	Not-Reportable
		Rash (Hypersensitivity / Rash)*	NS	Unlisted / Listed	Possible/ Unlikely	NUPR Reportable
			Relatedness Justification: Not Specified			
		Final Assessmment Text: <Final comments on assessment for this product license ... .>				
H	Augmentin (Lic2000)	Fatty acid deficient (Fatty acid deficiency / Fatty acid deficiency)	F	Listed / Listed	Unlikely / Unlikely	Not-Reportable
		Red Eyes (Ocular hyperaemia / Red Eye)	S	Unlisted / Listed	Unlikely / Possible	Reportable (7 day)
			Listedness Justification: Not Specified Relatedness Justification: Not Specified			
		Fever (No MedDRA Term)	LT	Unlisted / Unlisted	Not Related / Not Related	Not-Reportable
		Rash (Hypersensitivity / Rash)*	NS	Listed / Listed	Not Related / Not Related	Not-Reportable
		Final Assessmment Text: <Final comments on assessment for this product license ... .> Outline of Clinical Trials: 1) Indication: <Target Disease 1>; Development Phase: <DevPhase 1>; Subjects given this drug: <Yes/No> 2) Indication: <Target Disease 2>; Development Phase: <DevPhase 2>; Subjects given this drug: <Yes/No>				

3

Worklist

This chapter lists the changes that have been introduced in Worklist in the Argus Safety 7.0.3 release.

3.1 Literature Intake Updates

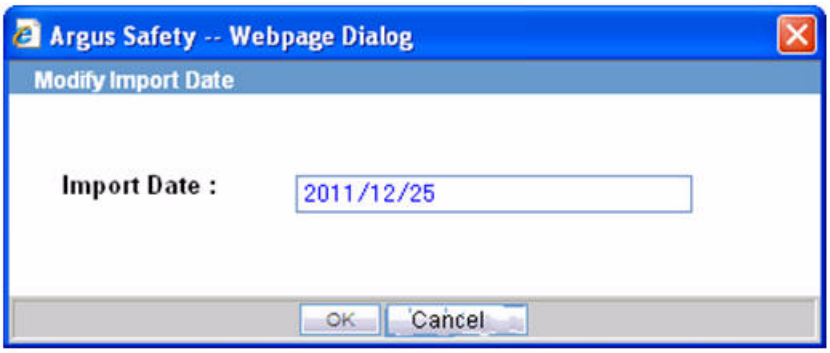
3.1.1 Import Tab Changes

- When the option "Assign User" is clicked in the Context menu of Literature Intake 'Import tab, Assign pop-up displays the active J user belonging to at least one User Group having access to Console ' Access Management ' Groups ' Menus ' Literature Intake menu option.
- A new column "Assessment Group" has been added to the Import tab with filtering and sorting capability.
  - Standard Argus Safety Type ahead has been provided for User group filter to display a list of user groups.
  - The system displays only those User Groups that are present in the records available on the screen.
  - The type-ahead field value is blank by default.
- Context menu in Import tab of Literature Intake screen contains the following new options. These options are added in the order / location as depicted in the screen mockup below.
  - Modify Import date
  - Assign User group
  - Modify Import date for multiple items

Figure 3–1 J Literature Intake - Import tab context menu

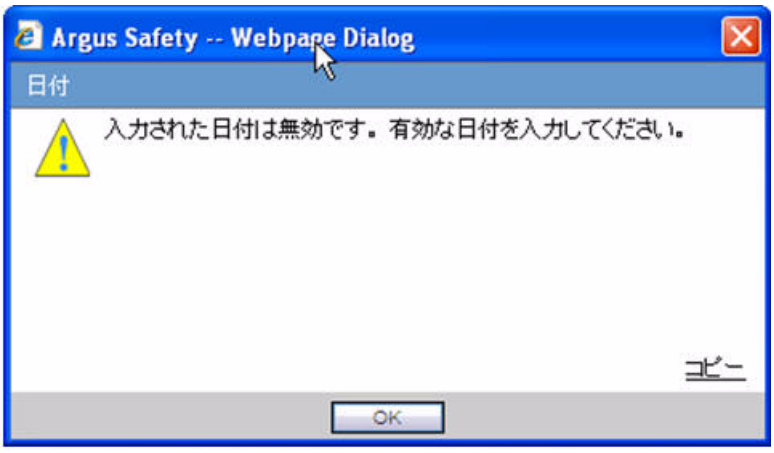
- On clicking 'Modify Import date', a dialog is opened with import date populated in a text box for the selected Literature intake record. Users can modify this date and use 'OK' to confirm or 'Cancel' to cancel the updates.

Figure 3–2 J Literature Intake - Modify Import Date



- Users can enter the date in Standard Japanese date format. Partial dates can not be allowed. The application displays existing standard Argus Safety error message box for not allowing partial date entry, as displayed below.

Figure 3–3 J Literature Intake - Message for Partial dates not allowed



- In case of any other error in modify import date action e.g. if user blanks out the date and click OK button, standard Argus Safety error message box is displayed with message - Modify Import Date failed.
- On clicking 'Modify Import date for multiple items' the same Modify Import Date dialog is displayed for all the items for which the checkbox in the first column is checked with default value as blank. Users can specify the modified import date which is updated for all the items for which the checkbox in foe first column was checked.
  - All standard validation related to partial or blank date is same as for the "Modify Import Date" action for single item.
- On clicking 'Assign User group', Assign User Group dialog is opened.
  - Standard Argus Safety Type ahead feature is provided to display list of user groups.
  - The system displays only those User Groups that have access to Console > Access Management > Groups > Menus > Literature Intake menu option.
  - By default, the value present in the base screen is displayed as selected value. If no value was present for this field in the base screen till now, then it displays blank as default value.
- "Assign User" and "Assign Literature Type" dialogs also display the already selected values as pre-populated when invokes these content menu actions to change these.

Figure 3–4 J Literature Intake - Assign User Group

- In case of any other error in assign user group action, standard Argus Safety error messagebox is displayed with message - 'Assign User Group failed'.
- User group selected in 'Assign User Group' dialog is displayed in 'Assessment Group' column in the base screen.
- Assessment Group is printed in the Print list report generated from Import tab.

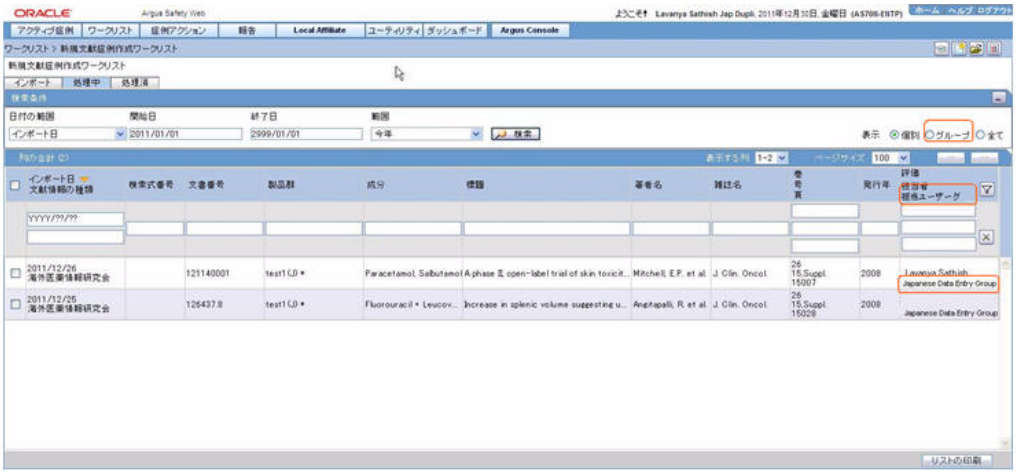
Figure 3–5 J Literature Intake - Import tab Print list

- The literature item is moved from the Import tab to the Processing tab on clicking the "Accept" option only when:
  - Literature is assigned to a User (existing functionality) or a User Group or both
  - Product Family is selected (existing functionality)
  - Literature type is selected (existing functionality)

3.1.2 Processing Tab Changes

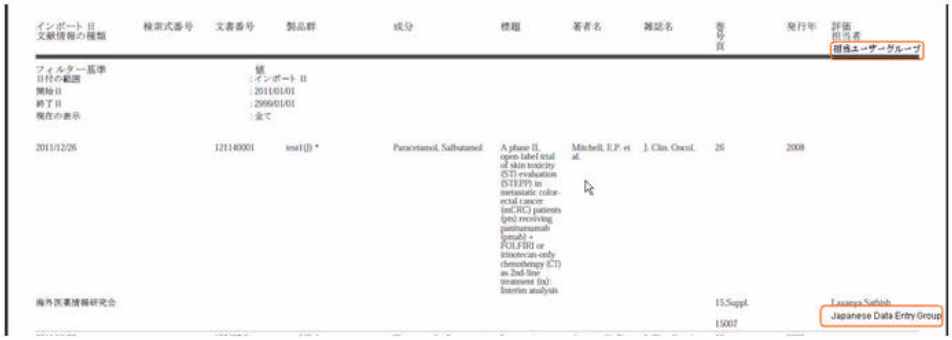
- A new column 'Assessment Group' has been added to the Processing tab with filtering and sorting capability.
  - Standard Argus Safety type ahead has been provided for User group filter to display list of user groups.
  - The System displays only those User Groups that are present in the records available on the screen.
  - The type-ahead field value is blank by default.
- User Group assigned in the Import tab for the Literature Intake record is displayed for the corresponding record in Processing tab.
- A new option 'Group' has been added to the View filter. The default option has been retained as 'Individual'.
- When 'Group' option is selected, the system displays cases based on the following logic:
  - Cases assigned to the current user
  - Cases assigned to users belonging to the same User Group as the current user
  - Cases assigned to User group to which the current user belongs

Figure 3–6 J Literature Intake - Processing tab



- Assessment Group is printed in the Print list report generated from Processing tab.

Figure 3–7 J Literature Intake - Print list from Processing tab



- If "Assessment" is not completed for Literature Data, and user selects the context menu option "Create case/Process unnecessary assessment", the system does NOT display error message 'Assessment result doesn't exist' and moves forward for case creation and displays the Book-in screen.
- If the case has been created without specifying the "Assessment" in the Processing tab, then "Processed" tab displays the values for "Assigned", "Assessment' and "Assesment Date" as blank.

3.1.3 Changes to Literature Duplicate Check

- A new column 'Assessment Group' has been added to the Duplicate Search screen - search results grid.
- When duplicate search is executed from the Case data, the 'Assessment Group' field value is left blank.
- When duplicate search is executed from the Literature Intake, assigned User Group is displayed in the "Assessment Group" column.

Figure 3–8 J Literature Intake -Literature Duplicate check

3.1.4 Changes to Existing Screen Label

- Import tab: Label "Asigned to" has been changed to "Assessment Owner".
- Processing tab: Label "Owner" has been changed to "Assessment Owner".
- Processed tab: Label "Owner" has been changed to "Screening Owner".
- Processed tab: Label "Assigned" has been changed to "Assessment Owner".
- These new labels are also reflected in their Print PDF output.

4

Reports

4.1 Reports: PMDA Expedited Reports

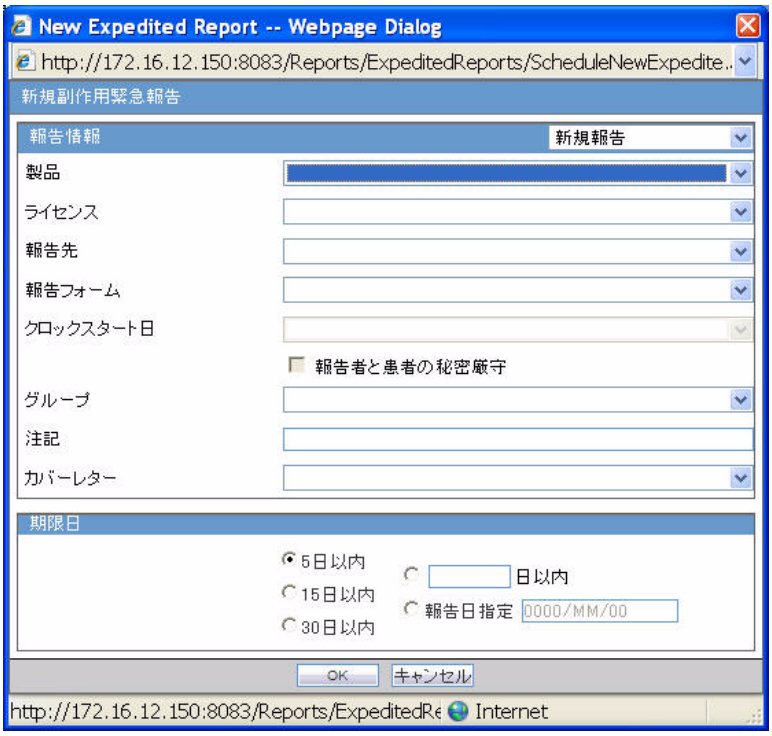
This section describes the J specific PMDA Expedited Report changes.

4.1.1 Manual Scheduling of Expedited Reports: New Expedited Reports Dialog Box

4.1.1.1 Functionality Changes

The following are the functionality changes for the New Expedited Reports Dialog Box (J Specific):

- Downgrade Report is scheduled manually using the New Expedited Report Scheduling User Interface.



- When you click **OK** with the Downgrade Reporting Schedule, the Justification window is displayed to log the reason of the downgrading.
- The **Schedule New Expedited Report** Window has a drop-down list in the top section. The content of the drop-down list has **New Report** and **Non-Reportable Follow up Report** options.
- When the Downgrade Report is scheduled, **J.8** is transmitted as **Does Not Apply**.

4.1.2 Paper Reports

Argus J is able to generate and submit 12 expedited paper report formats specified by PMDA for drugs.

PMDA forms for Marketed Drugs:

- Drug AE/Infection case report form 1
- Drug AE/Infection case form 2 (5pages)
- Surveillance report on drug, quasi drug, cosmetic case report form 3
- Surveillance report on drug, quasi drug, cosmetic case report form 4
- Surveillance report on measures taken for drug outside Japan such as production termination, recall, rejection, etc. form 5
- Surveillance report on measures taken for drug outside Japan such as production termination, recall, rejection, etc. form 6

PMDA forms for Investigational Drugs:

- Investigational product AE/Infection case report form 1
- Investigational product AE/Infection case form 2
- Surveillance report on investigational product research report form 3
- Surveillance report on investigational product research report form 4
- Surveillance report on measures taken for investigational product outside Japan such as production termination, recall, rejection, etc. form 5
- Surveillance report on measures taken for investigational product outside Japan such as production termination, recall, rejection, etc. form 6

Following are the Sections where Report Form List is used:

- Console J - Expedited Report Rules - **Form** section (irrespective of whether Japanese module is enabled or disabled)
- Schedule New Expedited Report dialogue - **Form** section (only if Japanese module is enabled)
- Medical Review - Preview of Expedited Report (only if Japanese module is enabled)

4.1.3 User Interface - Reporting Rules Configuration

This functionality allows configuration of Regulatory Reporting rules for scheduling Japanese reports.

The following are the functionality changes related to the PMDA Expedited reports:

- The **License Category** and **Reporting Category** fields are visible in Audit Log for Expedited Reporting Rules.

- The Reporting Rules algorithm has been updated to respect the License Category configured in Expedited Reporting Rules.
- The **Reporting Category** and **License Category** fields are printed below the **Cover Letter** field label under the **Expedited Report Rule Information** section of the print output.

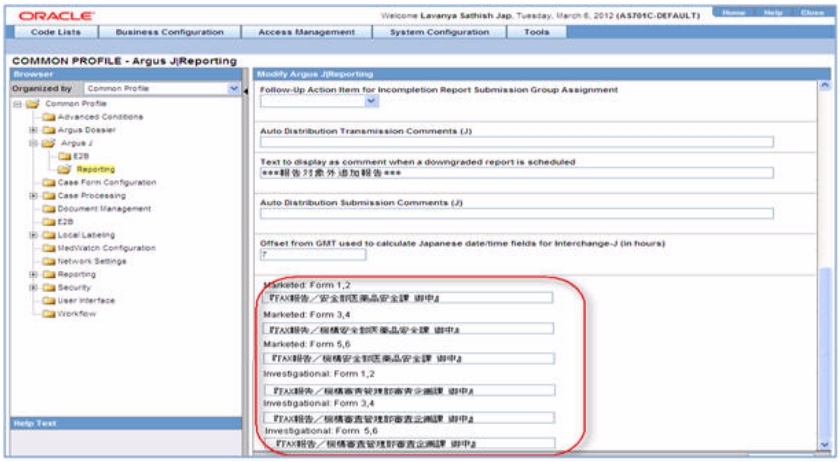
4.1.4 Additional Expedited Report Updates

The Expedited reports which are faxed to the PMDA need to be identified by which receiver is sending the information. This is done by the Additional Header information on the report output.

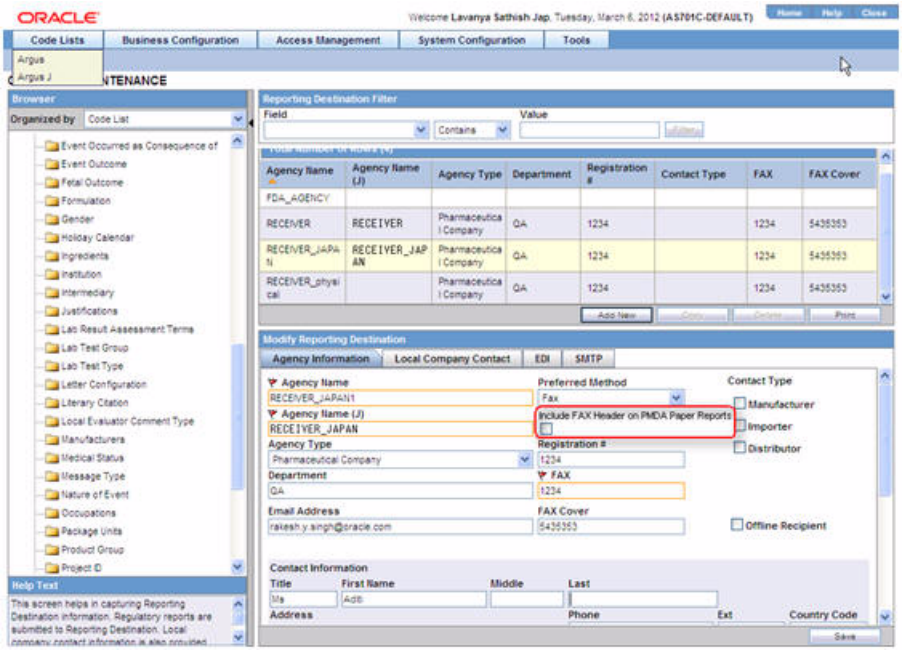
- The following profile switches are added to **Console** > **System Configuration** > **Argus J** > **Reporting**. These switches are specific to the Enterprise:

#	Field Label	Field Length
1	Marketed: Form 1,2	40
2	Marketed: Form 3,4	40
3	Marketed: Form 5,6	40
4	Investigational: Form 1,2	40
5	Investigational: Form 3,4	40
6	Investigational: Form 5,6	40

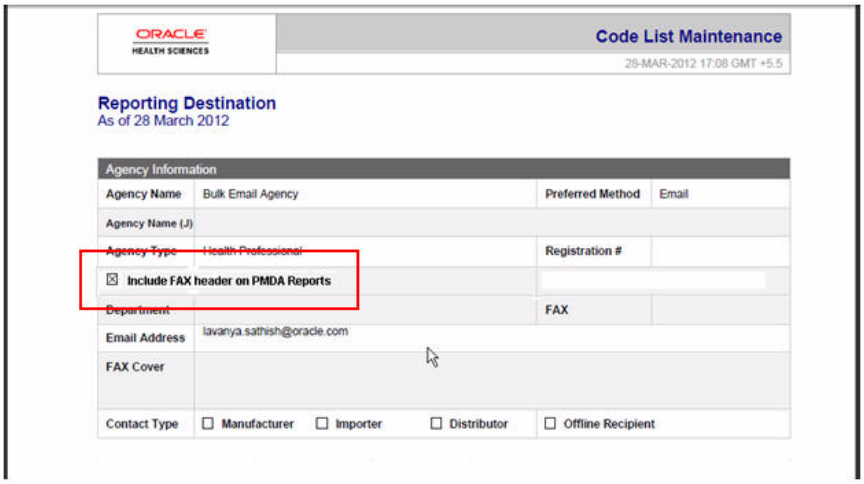
These switches are depicted in the following figure:



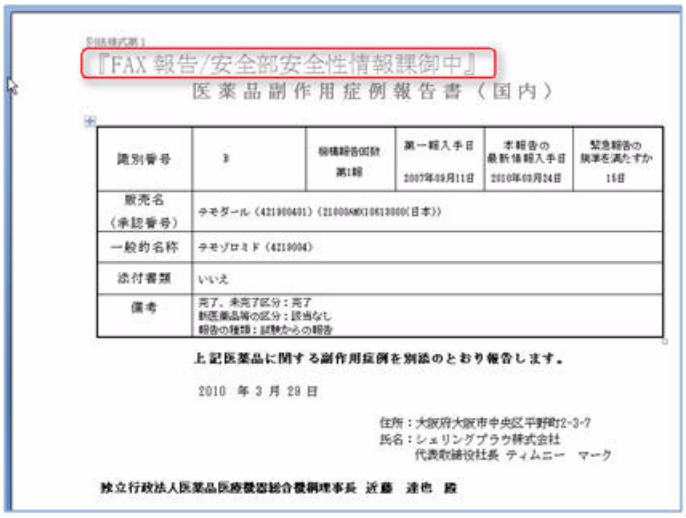
- The Reporting Destination Configuration has an **Include FAX Header on PMDA Paper Reports** Argus J user-specific checkbox on the **Agency Configuration** tab.



- This checkbox is enabled only when **FAX** is selected as the Preferred Method and is reset to disabled and blank when Preferred Method is set to something else.
- By default, this field is unchecked for existing and newly created Reporting Destinations.
- You can mark this option for a Reporting Destination and the changes made to this flag are audit logged and printed as part of Codelist Maintenance Print PDF.
- Fax header is printed only if the **Include FAX Header on PMDA Paper Reports** is marked for that Reporting Destination.



- Text entered in the Common Profile Switch is printed on the first page of the PMDA Paper Report:
  - Fax header text is printed in MS Mincho font of size 16.
  - Fax header text is printed in the line below the Report Format Number and is aligned to the left.


『FAX 報告/安全部安全性情報課御中』

医薬品副作用症例報告書（国内）

識別番号	3	機構報告回数 第1報	第一報入手日 2007年09月11日	本報告の 最新情報入手日 2010年03月24日	緊急報告の 該当を満たすか 15日
販売名 （承認番号）	テモダール（421900401）（21900AMX10613000(日本)）				
一般的名称	テモゾロミド（4219004）				
添付書類	いいえ				
備考	完了、未完了区分：完了 新医薬品等の区分：該当なし 報告の種類：試験からの報告				

上記医薬品に関する副作用症例を別添のとおり報告します。

2010 年 3 月 29 日

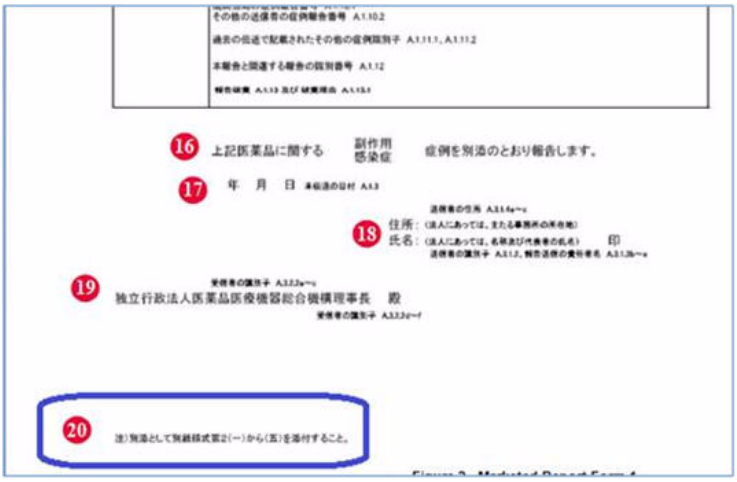
住所：大阪府大阪市中央区平野町2-3-7
氏名：シェリングプラウ株式会社
代表取締役社長 ティムニー マーク

独立行政法人医薬品医療機器総合機構理事長 近藤 達也 殿

– If you clear the Fax Header Text for the PMDA Paper reports in the Common Profile Switch, the header is left blank in the report.

Note printed on PMDA Paper Reports > Marketed Forms 1, 3 and 5 is removed as it is a data entry description (for FAX as well as when sent through Email) Report	**Note to be removed (English Translation)**
Marketed Form 1	Note: Format No.2(1) to (5) have to be attached
Marketed Form 3	Note: Form 4 should be attached together.
Marketed Form 5	Note: Attach Form 6 together.

The following figure depicts the PMDA Paper Report Sample:



4.1.5 PMDA Device Reports

1. Two new Japanese expedited device report forms have been added to all expedited report listing sections in Argus Safety.

- The following form options are displayed (in Japanese) to both English as well as Japanese users:

  Report Form 8: Medical Device Malfunction/Infection Case Report (Form 8)

  Report Form 10: Medical Device Research Report/Measure in foreign countries Report

- These form options are displayed to both Japanese as well as English users.
- These form options are supported at all the following locations in Argus Safety:

  Console J - Expedited Report Rules - Form Section (irrespective of whether Japanese module is enabled or disabled)

  Console J - Code list / Batch report generation (irrespective of whether Japanese module is enabled or disabled)

  Case Form - Toolbar - Draft (only if Japanese module is enabled)

  Schedule New Expedited Report dialogue - "Form" dropdown (only if Japanese module is enabled)

  Medical Review - Preview of Expedited Report (only if Japanese module is enabled)

  Create Unscheduled report (only if Japanese module is enabled)

  View Submitted report (irrespective of whether Japanese module is enabled or disabled)

  Bulk Report by Form (irrespective of whether Japanese module is enabled or disabled)

- These forms are not added to the Utility Blank Report Form User Interface as the Utility Blank Report Form feature has been deprecated from Argus Safety 7.0.1 release onwards.

2. These report forms open up in Microsoft Word format (.doc) from all the places in Argus Safety application as specified (but not restricted to) in the above specified list using the following forms provided by PMDA retaining all its fields, dropdowns and macros. However, these WORD forms are not meant to be edited and updated back into Argus Safety application.

   - The message box which prompts to ask the user if the expedited report will print blinded data or not is not displayed for these Japan Device Report Forms as there is no blinded data printed in these reports.
   - During Bulk Transmit Email process, these WORD report forms will not be merged even if Reporting Destination - Report Transmission Options have been configured to do so.

   Note: Merge feature is not required for these reports because the frequency of these Japan Device reports is quite low and there will hardly be any point of time when multiple WORD forms would exists in the system pending to be transmitted to a reporting destination.

3. These report forms are generated in Microsoft Word format (.doc) itself from both Draft and Final mode.

Note: These Japan Device Report Form 8 and 10 are not required to be supported on DLP case revision data as of now, because other PMDA Paper Reports and E2B are also not supported on DLP case revision data.

4. No mandatory field validation will be done during generation of these report forms, except for the following. All other validations are expected to be achieved by using Case Form Field Validations feature on the desired fields of the PMDA Device Information section.

   - If the value specified in Case form/Products tab/Device sub tab/PMDA Device Information section/Medical Device Reporting Category dropdown for the product for which the report is scheduled does not match with the allowed values for Form 8 or Form 10, then instead of opening the Report Form, application displays an error in the standard Argus Safety message box with OK button and the following message:

     'Case does not have matching device reporting category for the selected device report form'

   - The same error is logged as a report generation error, including if it occurs during background generation through Argus Safety Service. This error is also visible in the Report Details dialog - General tab at the bottom, as is displayed for the E2B generation errors.

5. Regulatory Reporting Rules Algorithm:

   - The Argus Safety Expedited Reporting Rules engine also considers "Device Reporting Category" dropdown value while matching rules against cases. It gets compared against the Case Form ' Products tab ' Device sub tab ' PMDA Device Information section ' Medical Device Reporting Category dropdown field value.

   - Argus Safety Expedited Reporting Rules engine scheduled the due date for these Japanese Device reports based on the Japan Aware Date, as configured in Reporting Destination configuration.

   - The Argus Safety Expedited Reporting Rules engine schedules only one Japanese Device Report for each matching rule, for each suspect device product in a case, even if the case has multiple Japanese Device Licenses of the same License Type in the Event Assessment tab of the case. It also respects the Reporting Destination configuration for "Suppress Duplicate Reports", as configured.

   - If multiple matching product licenses of the same device license type exist for a suspect device product in the Event Assessment tab, the license with the earliest award date of the matching product is considered for scheduling the report.

   - If the original product license for which the initial / previous follow-up report was scheduled is no longer available but another product license of the same product matching the same rule exists, then a follow-up report is scheduled in subsequent cycles instead of a downgrade.

     Downgrade is scheduled only when no licenses for that product matching that rule exist in the case.

6. Draft report view: The following logic is followed for PMDA Device Report Forms 8 and 10 to identify the product license when these reports are opened up in draft view, where no product license and reporting destination is not specified:

   - The Draft report view is applicable to the following areas:

     Toolbar - Draft icon

     Medical Review screen

   - It uses the first matching suspect device product as per the sort order of products in the case form products tab which has the matching "Medical Device Reporting Category" specified in the "PMDA Device Information" section.

     The following criteria is used to find matching Medical Device Reporting Category for the Japanese Device Form:

     Allowed Device Reporting Categories for PMDA Device Form 8:

     a. Malfunction without health damage

     b. Malfunction with health damage

     c. Infection

     Allowed Device Reporting Categories for PMDA Device Form 10:

     a. Research Report

     b. Measures in Foreign Country Report

     Earliest award date: Japanese marketed device active license (withdrawn date later than the Initial Receipt date) of such product is used.

     If Japanese marketed device license is not available, the Japanese investigational device license matching the above specified criteria is used.

     If no such Japanese device license is available for the matching product, then it considers matching any (irrespective of license country or license type) earliest award date active device license for the product.

     In case of multiple device licenses with same award date, it uses the license with the earliest internal license id (primary key) value.

   - If no product exists with the matching "Medical Device Reporting Category" for the Report Form, then instead of opening this form, the application displays an error in the standard Argus Safety message box with OK button and message - "Case does not have matching device reporting category for the selected device report form".

   - It uses the agency as specified in the Argus J common profile switch - "Default name of Regulatory Agency for Draft Expedited PMDA Reports" for such draft report views.

7. Manual Report Scheduling dialog for Argus J users is modified as specified below:

   If the user selects "Downgrade Report" as a dropdown option in the dialog header, then the "Report Form" dropdown list is updated to only display E2B and PMDA Marketed and Investigational Forms 1 - 6. Other expedited report forms or PMDA Device Report Forms are not displayed for "Downgrade Report" option.

4.2 Reports: PMDA Periodic Reports

In Japan, the PMDA accepts CSV format of Non-serious, Unlisted Periodic Report as well as paper format, and many pharma companies have started to submit using CSV forms. The following is the list of the functionality changes as a result of this requirement:

- PSR ReSD configuration is enhanced by adding parameter for generating Non serious, Unlisted PSR in Paper and CSV format.

Configuration Parameter	Validation Rule
Radio button with options Paper Report (FD Report)	When TBD is set to **Paper Report** in the **PSR Configuration** screen, Non-serious, Unlisted PSR(Form 7-1 and 7-2) are generated in the Paper Form. When TBD is set to **FD Report** in the **PSR Configuration** screen: The Form 7-1 and Form 7-2 checkboxes in the **PSR Configuration** screen are checked and disabled. The **Print the report content as Case Listing in the separate paper** PSR Configuration parameter is unchecked and disabled. Non-serious, Unlisted PSR (Form 7-1 and 7-2) are generated in CSV format. The Form 7-1 is generated in Paper format along with other PSR/ ReSD forms.

- The radio button is set to **Paper Report** in the existing PSR Configuration for an upgraded database , if Form 7-1 or Form 7-2 is marked.
- The Argus Safety standard Advanced Conditions control (as present in English Periodic Reports) is provided in **PSR ReSD Configuration** screen for inclusion/ exclusion of cases for all forms of PSR and ReSD reports.

UI Element	Validation Rule
Dropdown	The drop-down list displays the default options: **None** and **New** in the drop-down list. **None** is displayed by default. The Advanced Condition names are displayed in the alphabetical order. On specifying an Advanced condition, the system runs the query on the cases retrieved from Product selection and Reporting Time frame.
Advanced Condition Lookup button	The **Advanced Condition Lookup** dialog box is displayed on clicking this button.

UI Element	Validation Rule
AC	On clicking the **AC** button, the system displays a message with **Yes**, **No**, and **Cancel** buttons. If you select **Yes** , the system displays the **Advanced Condition Query Set** screen. If you select **No**, the system displays the **Advanced Condition** screen. If you select **Cancel**, the system closes the message. If you do not have rights to create or modify AC's , the **AC** button on the **Japanese Periodic Report Configuration** screen displays the following message in Japanese: You do not have the rights to create new Advanced Conditions. If there is no AC specified in **Japanese Periodic Configuration** screen, the Advanced condition (None) is printed. If there is an AC specified in **Japanese Periodic Configuration** screen, the Advanced condition(<AC Name>) is printed. .

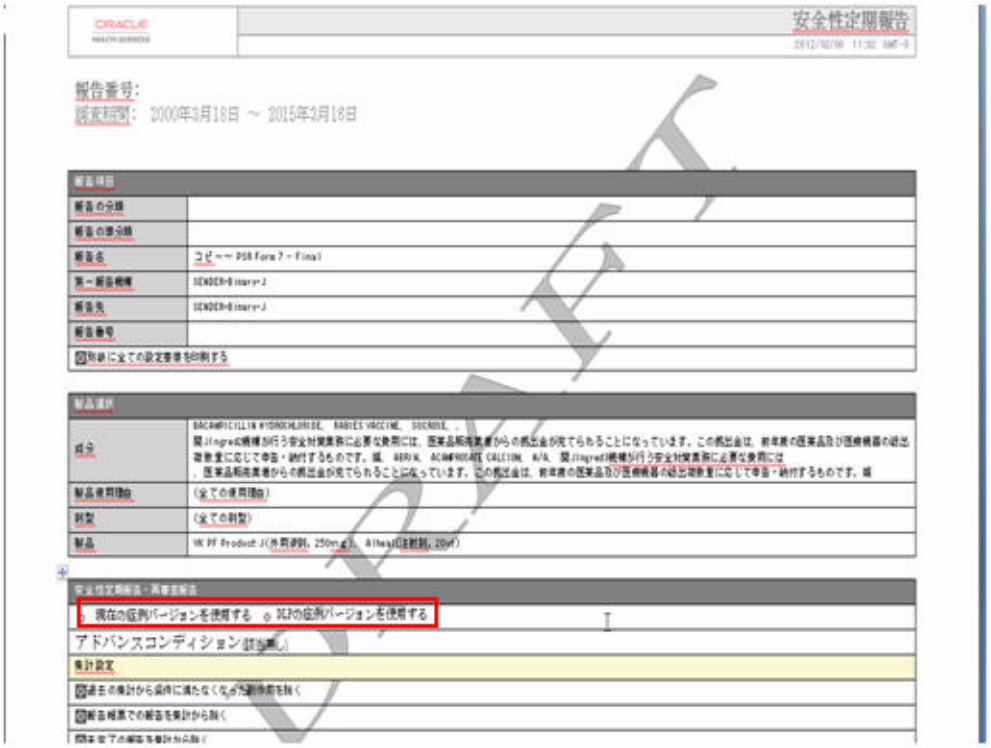
- The Data population logic of FD report is the same as that of the Paper Report.

4.2.1 DLP at Report Level

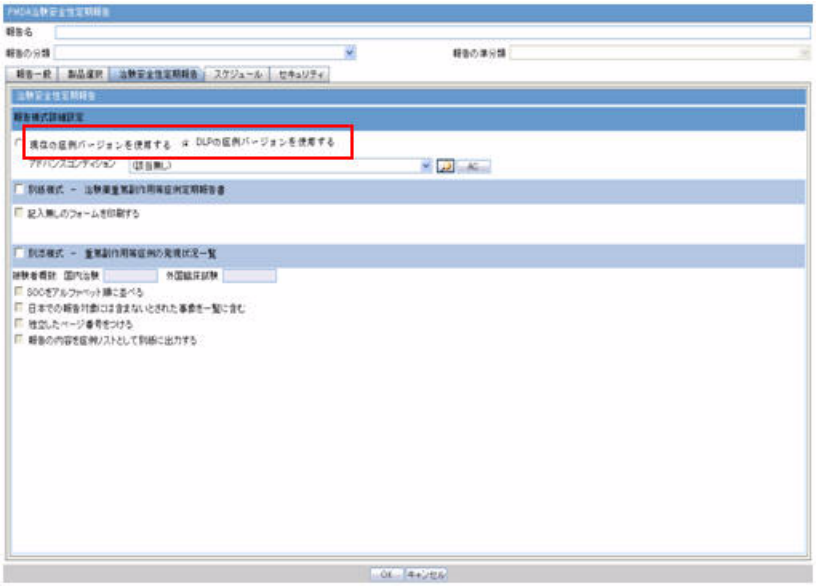
- The **DLP Configuration** radio buttons, **Use Current Case Version** and **Use DLP Case Version** is moved to the Report level for PSR/ReSD, CTPR, and Seiyakukyo reports. The **PSR/ReSD Report Configuration** screen is shown below:

- These radio button options are displayed only when DLP is enabled.
- The **DLP Configuration** radio buttons, **Use Current Case Version** and **Use DLP Case Version** are moved to the Report level in the Configuration Print Report of

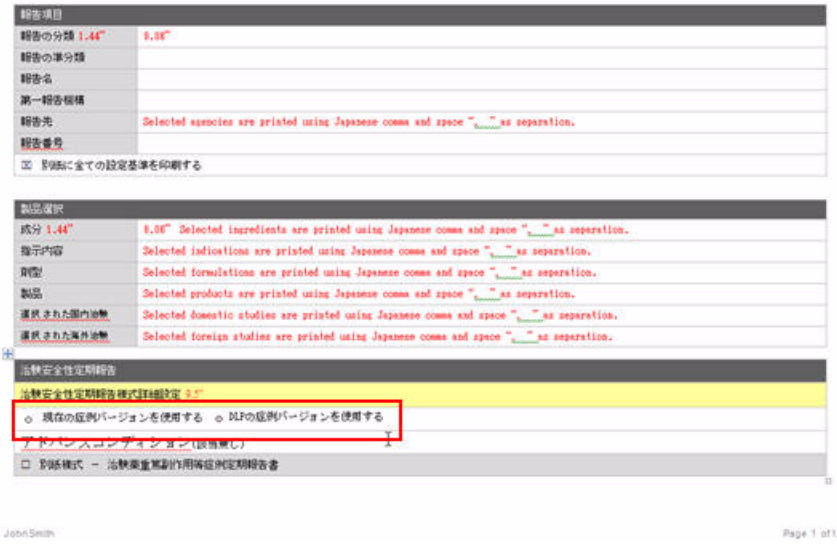
PSR/ReSD, CTPR, and Seiyakukyo reports. The **PSR/ReSD Report Configuration** print is shown in the screen below:



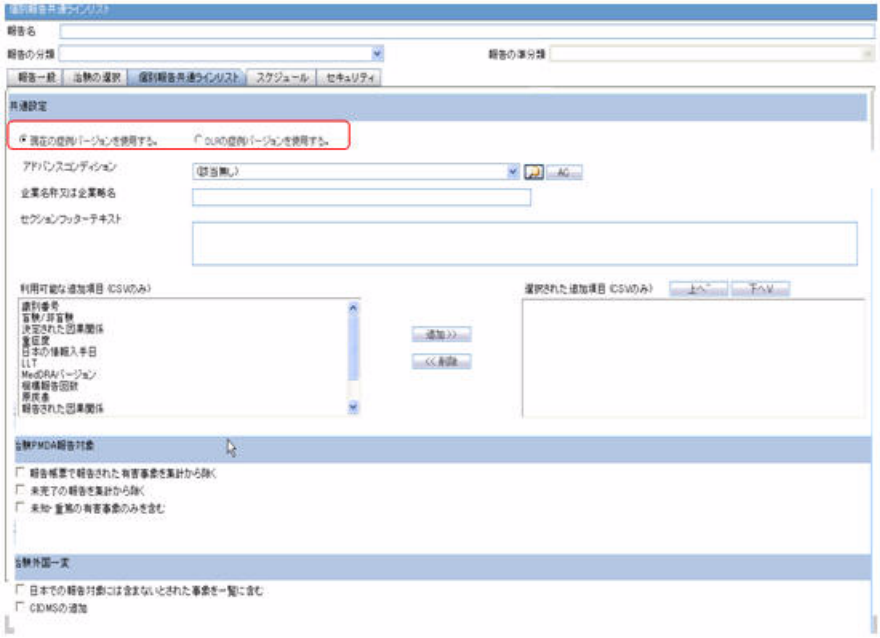
- The **DLP Configuration** radio buttons, **Use Current Case Version** and **Use DLP Case Version**) are moved to the Report level in the **CSPR Report Configuration** screen, as shown in the screen below.
- These radio button options are displayed only when DLP is enabled.



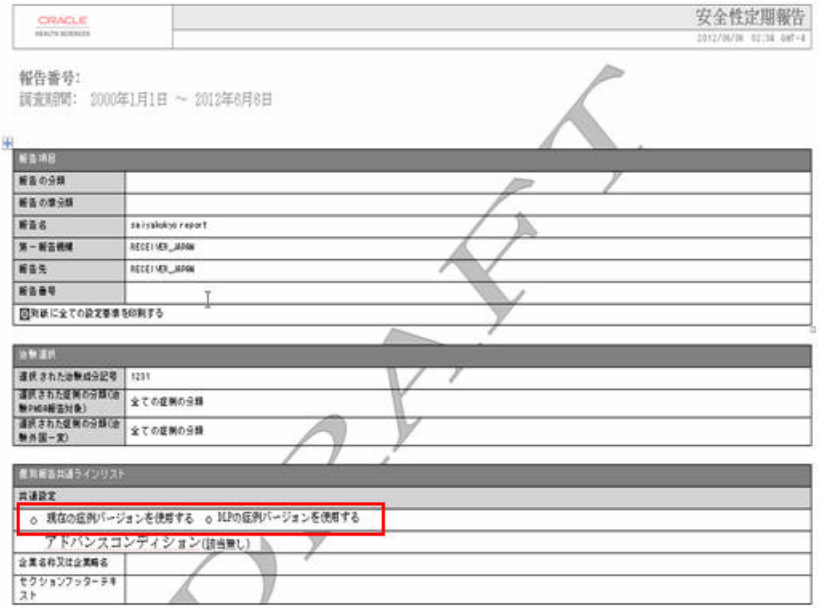
- The **DLP Configuration** radio buttons, **Use Current Case Version** and **Use DLP Case Version** are moved to the Report level in the CSPR Report Configuration print, as shown in the screen below.



- The **DLP Configuration** radio buttons, **Use Current Case Version** and **Use DLP Case Version** are moved to the Report level in the **Seiyakukyo Report Configuration** screen, as shown in the screen below.



- These radio button options are displayed only when the DLP is enabled.
- The **DLP Configuration** radio buttons, **Use Current Case Version** and **Use DLP Case Version** are moved to the Report level in the Seiyakukyo Report Configuration print, as shown in the screen below.



4.2.2 Upgrade Considerations

In the upgraded database, the DLP Configuration radio buttons at Report level are set as per settings of the parameter at Form level (prior to upgrade) for the PSR/ReSD, CSPR, and Seiyakukyo reports.

4.2.3 Advance Conditions in J Periodic Reports

- The following changes are made to the Japanese Periodic reports when Advanced condition is used for filtering cases along with **Use DLP Case version**.
  - ACs are applied on DLP case data for all forms of PSR/ReSD, CSPR, and Seiyakukyo reports:

    If the PSR/ReSD has the **Exclude events which don't meet the condition from the past data** option checked, the ACs are applied as of the end date of the latest reporting period for the previous reporting period cases in the PSR: Forms 3-4 and ReSD: Forms 4-5.

    If the PSR/ReSD has the **Exclude events which don't meet the condition from the past data** option unchecked, the system fetches the past data as per the existing functionality (without applying AC).
- On clicking the **Print** button in the **PSR Configuration** screen for generating Draft or Final PSR report:
  - The system displays the following message:

    Report submitted to Background Report Processing. Please view the status of the Report from **Reports** > **Periodic Reports** > **Background Periodic Report Status** screen.
  - Upon generation of the Report, the following links are displayed in the PSR Configuration screen:

    FD Reports

DRAFT link for PSR Paper report(along with Form 7-1) and CSV 1, 2, 3 links for Forms 7-1 and 7-2 OR

FINAL link for PSR Paper report(along with Form 7-1) and CSV 1, 2, 3 link for Forms 7-1 and 7-2

Paper Form report (Existing functionality)

DRAFT link for PSR Paper report OR

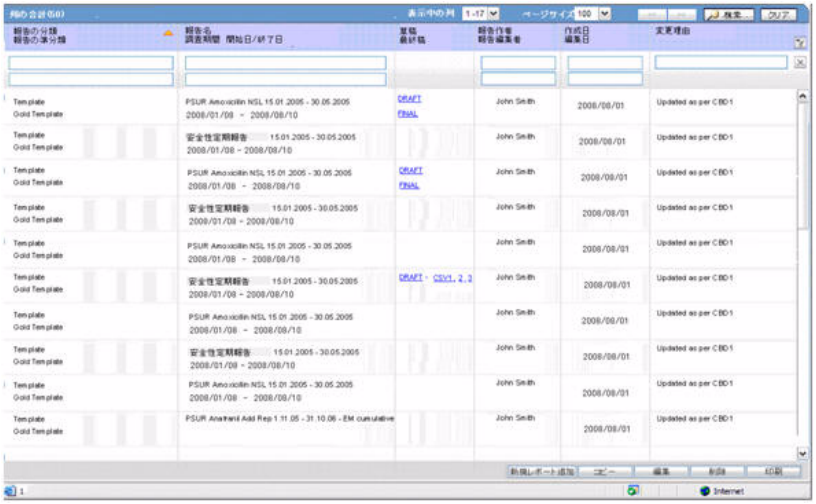
FINAL link for PSR Paper report

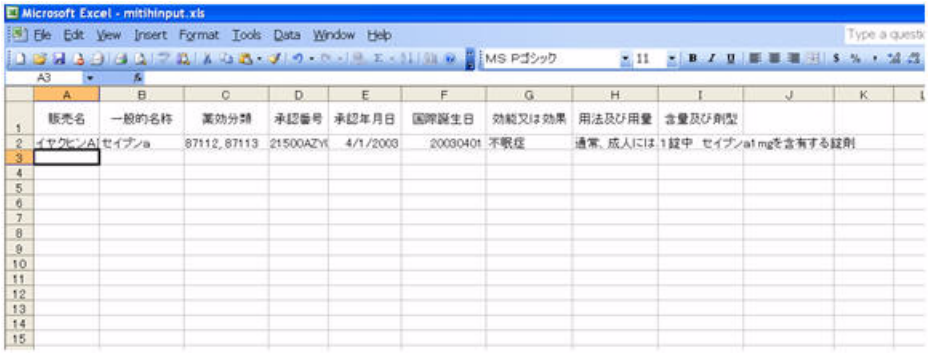
- PSR Paper report is opened in IE window on clicking on DRAFT or FINAL links.
- On clicking the links **CSV1, 2, 3**, the system displays the corresponding CSV file in MS Excel.

The following table illustrates the PSR ReSD Report Library:

Field separation	Comma(,)
Text separation	Double Quotation("")
File Naming convention	File name of Final CSV is as follows: COMPANY_ABBREVIATION_NAME-YYYYMMDD-001_1_{Randnum}.csv COMPANY_ABBREVIATION_NAME-YYYYMMDD-001_2_{Randnum}.csv COMPANY_ABBREVIATION_NAME-YYYYMMDD-001_3_{Randnum}.csv The 3 digit number is incremented when more than one report is generated on the same day for the same company. COMPANY_ABBREVIATION_NAME is **Company Identifier** in **Codelist** > **Reporting Destination** > **EDI** COMPANY_ABBREVIATION_NAME-YYYYMMDD-00X is printed on the bottom of the form 7-1 Paper report. Randnum is a system generated number and is not printed on the 7-1 Paper report. The file name for the Draft report is as per Argus Safety.

The following figure depicts the Form 7-1 in CSV format:





- On generating Form 7-1, 7-2 in FD format, 3 CSV files are generated.
- Data printed in CSV file1 is mentioned below:
  - These field values are printed as it is, as in the PSR Form 7-1 PDF Output unless specified.
  - In case of multiple licenses for a product, each product license and all the corresponding field values are printed as a separate row.
  - During Report generation, data is truncated if it exceeds the field length specified in the Report Mapping table below:

English Title	Field Length	Data Property
Trade Name	100J	The Trade Name of each product is printed in a separate row and numbering is not used.
Generic Name	1000J	The Generic Name of each product is printed in a separate row, and numbering is not used.
Drug Classification	35AN	The Drug Action Classification is printed in a separate row and numbering is not used.
License Number	16AN	The License Number is printed in a separate row and numbering is not used.
Award Date	200J	The Japan Award date is entered in the **MM/DD/YYYY** format. If the Month or Day value is less than 10, it prints without **0**. For example, **8/1/2011**. Award date of each Product is printed in a separate row and numbering is not used.
IBD	8N	The International Birth Date is printed in **YYYYMMDD** format. IBD of each Product is printed in a separate row and numbering is not used.
Indication	5000J	The logic of printing data is the same as **Paper Report- Column - Indication** The Indication of Product is printed in a separate row and numbering is not used.

English Title	Field Length	Data Property
Use	5000J	It is populated by default value.
Quantity and formulation	5000J	The logic of printing data is the same as **Paper Report- Column Amount and Formulation**

- Data printed in CSV file 2 is as follows:
  - These field values are printed as it is in the PSR Form 7-1 PDF Output, unless specified.
  - During Report generation, the data is truncated if the data exceeds the field length specified in the Report Mapping table below:

English Title	Field Length	Data Property
Investigational time frame	17N	The Investigational Unit Timeframe is printed in the following format: YYYYMMDD-YYYYMMDD For single digit values for MM and DD, leading **0** is added.
Aware date	8N	Reporting Timeframe starting date (Assigned Date) is printed in the following format: YYYYMMDD For single digit values for MM and DD, leading **0** is added.
Action taken for ensuring safety and planned action for safety based on the static data	10000J	This field is used to enter the description in the output format.
Note	5000J	This field is used to enter the description in the output format
MedDRA version number	4N	The latest MedDRA J version configured in Console is printed. For example, 13.1
Report date	8N	It is printed as the current database date converted into Japan time zone (by using the common profile switch under **Argus J** > **Reports** > **Offset from GMT** used to calculate Japanese date/time fields (in hours)) on which the report is being executed. It is printed in the following format: YYYYMMDD For single digit values for MM and DD, leading 0 is added. The above logic is used in Paper Report also.

English Title	Field Length	Data Property
Address	200J	Sender Address: A.3.1.4a-c in the following format: [A.3.1.4c][A.3.1.4b][A.3.1.4a]. It is printed as a single line with no line breaks or spaces between these field values.
Name	100J	Name of person responsible for sending report A.3.1.3b-e in the following format: [Company Name (J)] [A.3.1.3b]space[A.3.1.3e]space[A.3.1.3d] space[A.3.1.3c]. A.3.1.3 is printed as a single line with no line breaks. Line break between [CompanyName(J)] and {A.3.1.3}

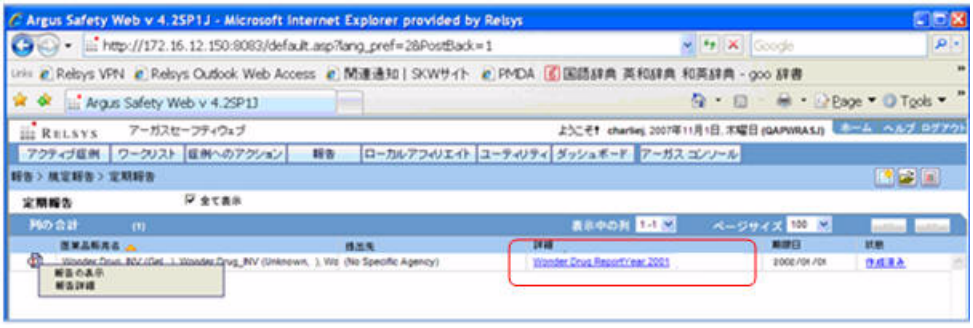
- Data printed in CSV file 3 is as follows:
  - These field values are printed as it is in the PSR Form 7-2 PDF Output, unless specified.
  - During Report generation, the data is truncated if it exceeds the field length specified in the Report Mapping table below:

English Title	Field Length	Data Property
Number	20AN	The logic of printing data is the same as **Paper Report- Column Number**
Preferred Term	100J	The logic of printing data is the same as **Paper Report- Column Preferred Term**
MedDRA code	8N	The logic of printing data is the same as **Paper Report- Column MedDRA Code**
Gender	1N	It is printed based on the **Case Form** > **Patient** tab > **Gender** field value The following is printed: 1 for Male 2 for Female 3 for Unknown and NULL
Age (Value)	5N	Age (Value) for **B.1.2.2a** E2B element Leave the field blank when this is unknown.
Age (Unit)	3N	Age (Unit) for **B.1.2.2b** E2B element Leave the field blank when this is unknown.

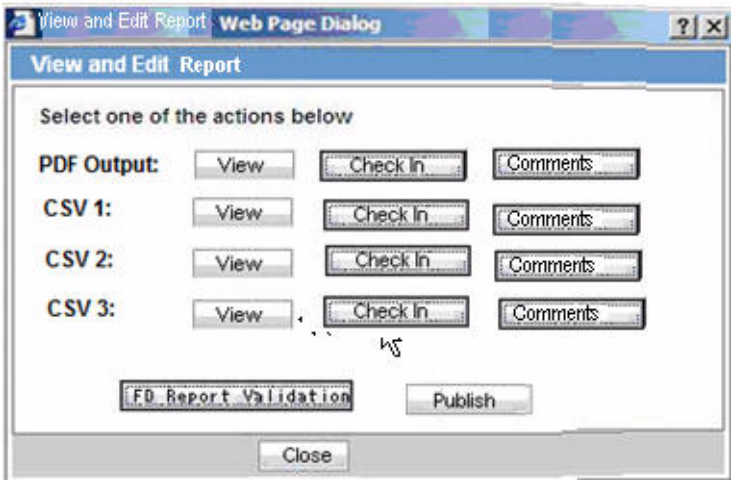
English Title	Field Length	Data Property
AE Occurring Date (Value)	8N	The Year and Month of AE is printed in the following format: YYYYMMDD YYYYMM YYYY Leave the field blank when this is unknown.
AE Occurring Date (Unit)	3N	The Year and Month of AE is printed in the following format: 102 for CCYYMMDD 610 for CCYYMM 602 for CCYY Leave the field blank when this is unknown.
Outcome	1N	Event outcome based on the E2B code for B.2.i.8 element.
Report Type	1N	
Note, Trade Name	100J	This field is used to enter the J drug code. When the code is not available, enter the Product Name (J).
Note	1000J	If this non-serious, unlisted adverse event was reported in individual expedited report during the investigational time frame, enter the reports (PMDA Acknowledgment Number). When the event was reported in multiple safety reports, all the PMDA Acknowledgment Numbers are printed in this section, by printing each ID one below other in different lines. Leave the field blank if there is no data to output. Example: 2-05030000 2-05030011

	A	B	C	D	E	F	G	H	I	J	K	L
1	番号	基本語	MedDRAコード	性別	年齢（値）	年齢（単位）	副作用発現年月日（値）	副作用発現年月日（単位）	転帰	報告の種類	医薬品	備考
2	1	腰痛	10000081	1	4	800	20050920	102	1	1	399040001	識別番号：2-05030000

- Upon generation of the Final PSR Report in FD format, the Report link is displayed in the **Reports** > **Compliance** > **Periodic** screen.



- The View Report option for the Japanese Periodic reports is renamed as **Edit and View Report**.
- On clicking **View and Edit Report** for the mixed PDF and CSV PSR Report, the **View and Edit** dialog box is displayed with separate options to view PDF and CSV report.



- On clicking **View and Edit Report** for the PSR Report (Paper format), CSPR, and Seiyakukyo reports, the **View and Edit** dialog box is displayed by hiding the following:
  - Label: Select one of the actions below
  - Labels: CSV1, CSV2, CSV, and its corresponding Checkin/Checkout and Comments buttons.
  - Button: FD Report Validation

English Label Name

View and edit PSR/ReSD

Properties

Title

English Label Name

Select one of the actions below:

PDF Output

CSV1

CSV2

CSV3

Properties

Fixed labels

English Label Name

View

Properties

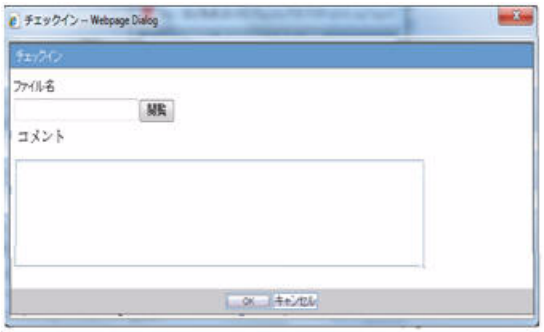
- This button is always enabled (regardless of the **Checkin/Checkout** status) for all users.
- On clicking the **View** button for CSV report before/after Publishing, the system opens the CSV Report in Excel in Read-only mode.
- On clicking the **View** button for Paper report before Publishing, the system opens the report in Word.
- On clicking the **View** button for Paper report after Publishing, the system opens the Final report in PDF format.

English Label Name

Checkin

Properties

- This button allows you to check-in the individual reports.
- When the **Checkin** button is clicked for a CSV report, the Argus Safety standard **Checkin** dialog box is displayed.
- The **Check In** dialog box captures the comments for 255 characters.



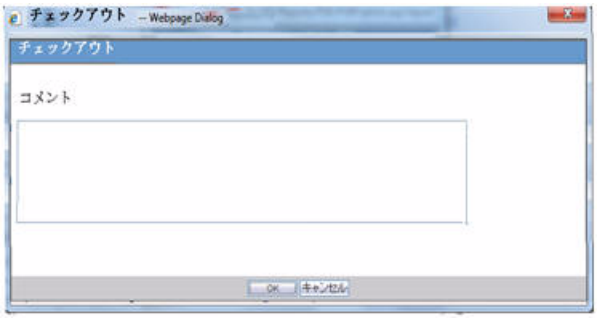
- The system allows you to specify only **.csv** files in the **Filename** field. If you upload some other file type and click **OK**, the following standard message application is displayed by this common file upload control:
  This is not valid file to upload. Allowed file types are {X}
- When the **Check-in** button is clicked for a Paper report, the Argus Safety standard **Checkin** dialog box is displayed to specify the report file name and Checkin Comments.
- The system allows only **.doc** files to be specified in the **Filename** field. If you upload some other file type and click **OK**, the following standard message is displayed by this common file upload control:
  This is not valid file to upload. Allowed file types are {X}

English Label Name

Checkout

Properties

- After the report is checked-in, the **Checkin** button is changed to **Checkout**.
- The **Checkout** button is disabled after the report is published.
- Only one user is able to checkout a report.
- When the **Checkout** button is clicked for a paper report or CSV report, the system displays the **Checkout** dialog box:



- The **Checkout** dialog box allows you to specify the checkout comments of a maximum size of 255 characters.
- **OK** and **Cancel** buttons are provided in the **Checkout** dialog box:
  - The **Cancel** button cancels the Check Out operation and closes the **Checkout** dialog box.
  - On clicking the **OK** button for a Paper report, the system opens the report in Microsoft Word in the Update mode.
  - On clicking the **OK** button for CSV report, the system opens the report in Microsoft Excel in the Update mode.
- After the report is checked out, the **Checkout** button is changed to **Checkin**.
- The same user uses this button to checkin the revised checkout file. For other users, this button becomes disabled as long as it is checked-out by the original user.
- If you open the **Checkout** dialog box and completes the Check Out operation after sometime (after another user has already checked - out the report), the following message is displayed:

  Report cannot be checked-out as it is in use by another user

English Label Name

FD Report Validation

Properties

- This button is enabled only after all the CSV and WORD reports are checked-in at least once. When this button is clicked, data in all the CSV files are validated.

  When there are no error messages, the Argus Safety standard message box with message -

  No problem was found in the report is displayed with an **OK** button.

- The following validation is executed and the errors are displayed in the form of PDF report.
  - The character check is executed. If there is invalid character specified:

    (Item [X-X], Row YY: Invalid character is used)

    N (Numeric) - Only **0-9**, **.**, **E**, **+**, and **-** that are used for displaying integers or floating point representation are allowed. Full-width characters are not allowed.

    AN (Alpha Numeric) - half-width (1byte) alphabet, Numbers and special characters specified in Argus J common profile switch - **Characters to be allowed to use in AN (Alphanumeric) E2B items** are used. Full-width (2byte) characters are not used.

    J (Japanese) (100J mean 50 double byte J chars) - Full-width characters and AN are used which is same as E2B J validation. Characters specified in Argus J common profile switch - **Additional invalid character to be checked in Japanese character validation** is considered.
  - Field length check is executed. If there are more characters than the maximum length, the following message is displayed:

    (Item [X-X], Row YY: Numbers of characters is exceeding the defined maximum value.)
  - The data format for data items 1-5,1-6,2-1, 2-2, 2-6 in above **Data Property** is checked, and when format is not correct, the following message is displayed:

    (Item [X-X], Row YY: Data format of the column is invalid)

    The Validation errors belonging to the data from the CSV files are listed separately. The errors within the CSV file are listed category wise such as Character check, Field length, and Data Property. If there are no errors for all property checks for a CSV file, **No problem was found in the report** is printed below the CSV#.
- The following validation message in FD Validation report is displayed, when column in CSV does not match with the format specified by Regulation:

  The structure of the columns in the CSV file is not in required format

  This validation is verified first on clicking **FD Report Validation** button. If the structure of the CSV file is not in required format, the further validations are not checked for that CSV file.

English Label Name

Publish

Properties

- The **Publish** button is enabled only after all reports are checked-in at least once.
- This button is disabled when any of the report is checked out.
- When the report is not published, you can check in/checkout the report as many times as you want.
- After the **Publish** button is executed and the PDF file is created only for Paper report, the system automatically opens only the Paper report on the UI. In addition, the **Check-in / Check-out** button is disabled and the label is changed to **Check-out**.

- The **Publish** button converts the checked-in Paper report in word document to the PDF file as it is with the same layout. The CSV report that is checked in remains as is and is not converted to PDF.
- Once **Publish** is done, the Paper report in word format of the report is no longer available from the **Final** link and the PDF format overwrites the generated/updated Word format in the database. The **Draft** link generates the fresh report in Microsoft Word format.

English Label Name

Close

Properties

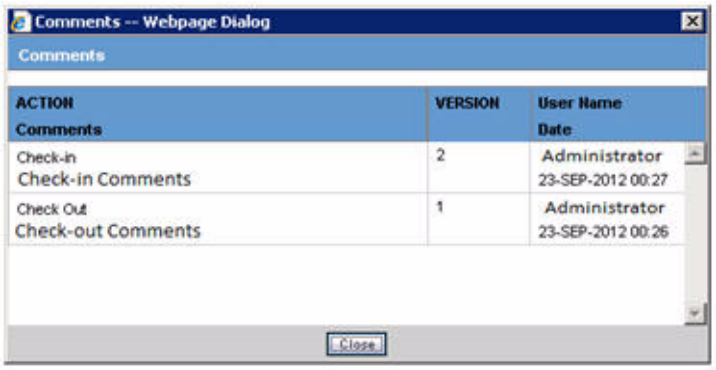
On clicking this button, the system closes the **View and Edit Report** dialog box.

English Label Name

Comments

Properties

- On clicking this button, the **Comments** dialog box is displayed with the Check-in/Checkout comments.
- The comments are displayed pertaining to the PDF/CSV for which **Comments** button is clicked.



- The **Comments** dialog box displays the Version Number, Username, Action, Date(Time stamp in User Local date with GMT offset), and Comments entered in the descending order of the Dates.
- Version of the first check-out is considered version 1.
- Version number is incremented on every Check-in.
- Version number is not displayed for subsequent checkout (after first checkout).
- The **Comments** dialog box is closed on clicking the **OK** button.

- The Report Submission process is the same as other PSR forms.
- The following Common Profile Switches are moved from **Common Profile Switch** > **ARGUSJ** > **E2B** to **Common Profile Switch** > **ARGUSJ** > **Reporting in Fresh and Upgraded database**.
  - Additional invalid characters to be checked in Japanese character validation.
  - Characters to be allowed to use in AN (Alphanumeric) E2B items.
  - Perform Japanese character validation at E2B Check and E2B Report Generation.
- The **Perform Japanese character validation at E2B Check and E2B Report Generation** Common Profile Switch is renamed as **Perform Japanese character validation at E2B Check, E2B and Periodic Report Generation**. This change in the Common Profile Switch is applicable for upgraded database.

Note: In the future, all periodic report will have the same CSV format options.

4.2.4 Check in/Checkout Enhancements

Checkin/Checkout dialog box changes described above for PSR/ReSD reports are applicable for the following Japanese reports:

- CSPR
- Seiyakukyo Report

4.2.5 Other Changes

The **TEXT_J** data for TRANSLATION_ID ='User Name' is misspelled in **LM_TRANSLATION_LABEL** table.

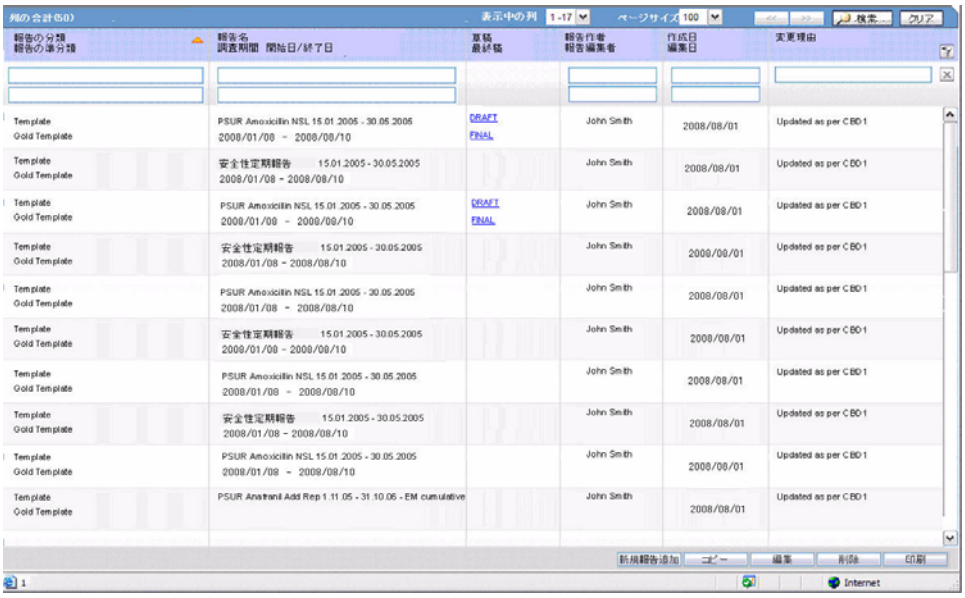
4.2.6 Periodic Safety Report

4.2.6.1 Format

The system allows the definition of PSR reports for products. The purpose is to define a fixed set of PSR reports for PRIMARY AGENCY (the various regulatory authorities as optional) and then associate products with these reports. The PSRs can then be scheduled automatically.

PSR applies only for Japanese licenses.

- The system contains a configuration screen to define a PSR report. A new menu item, **Reports** > **Periodic Reports** > **PSR/ReSD** Reports is created. When this is clicked, the following page is displayed.



Field Name	Description
Category	
Sub Category	
Report Name	
Inclusion Start Date/Stop Date	
DRAFT / FINAL	
Author Created	
Author Modified	
Date Created	
Date Modified	
Justification	
Search	
Clear	
Total Number of Rows ( )	
Displaying Rows	
Page Size	
New Report	
Copy	
Modify	
Delete	
Print	

PSR Main Window

- If the report is being currently opened by another for modification, the system displays the following message:
  The report which is selected is being used by XXXX and cannot be modified.
  where XXX is the full user name of the user has opened it.
- The labels and buttons related to the CSV files and FD validation reports are hidden in the **Edit and View Report** dialog box invoked for the PSR Report (Paper format), CSPR, and Seiyakukyo reports.
- The **Create from Template** button that is available on **Argus E PSUR and CTPR** section is not added for Japanese PSR, ReSD configuration.
- This page displays a list of the PSR reports stored in the system.
  - You can add a new report by clicking on the **New Report** button.
  - The **Copy** button makes a copy of an existing report:

    When you copy an existing PSR Report, all the configuration of the report including timeframe rows are copied.

    Report Name of new copy has **copy of** in front of the name.

    When the configuration is copied, the past dates in the schedule frequency, JAD, IBD, and Assigned date are also copied as read-only. The other sections of the copied configuration are editable.

    When you copy an existing non-submitted PSR report, all the configuration including timeframe rows are copied. As the original report is non-submitted, all the timeframe rows are retained as non-editable or editable as they were in the original PSR. The JAD, IBD, and Assigned Date become editable or non-editable depending upon if there are timeframe rows in the copied PSR which are non-editable.
  - The **Modify** button displays the report definition.
  - The **Delete** button allows you to delete a report after displaying the following confirmation message:
    Proceeding to Yes will remove the report configuration. Proceed?
  - Clicking **Print**, results in displaying a new dialog prior to report preview allowing you to select from several preview or direct export options: Word output.
- The **Delete** option is only available if there are no final reports generated for the Periodic Reports. The Delete option only hides the report from the list.
- In the recently executed **Periodic Report** section, a link is available for the last executed report only if the Report is still available on the Report Server.
- Clicking **New** or **Modify** in the above screen displays the PSR Configuration Window.
- Once the state of the report is changed to **Submitted**, you cannot update the configuration of that PSR. This is done by disabling the **OK** button. For example, when the state is un-submitted, the report is editable again. In addition, when the non-editable configuration is opened, the following warning message is displayed:
  This configuration is not modifiable because the status of this Periodic Safety Report is Submitted
  When you click **OK**, this displays the Configuration window.
  When you click **Cancel**, the configuration window is not displayed.
- When the status of the report is **Submitted**, only the configuration page is printed.

- The Copy can be done any time while the configuration exists.

  When you create PSR after 2nd time, the new copy of the configuration is required. You can then modify the content to print the current PSR.

- Before saving the PSR configuration, Report Name, Primary Agency, Product Selection, and at least one time frame need to have a value entered.

  When these are not entered, the following messages are displayed:

  When Report Name is not entered:

  Report Name is not entered

  When Primary Agency is not entered:

  Primary Agency is not entered

  When selected product is not available:

  Product is not selected

  When At least one time frame is not entered:

  Investigation time frame is not configured

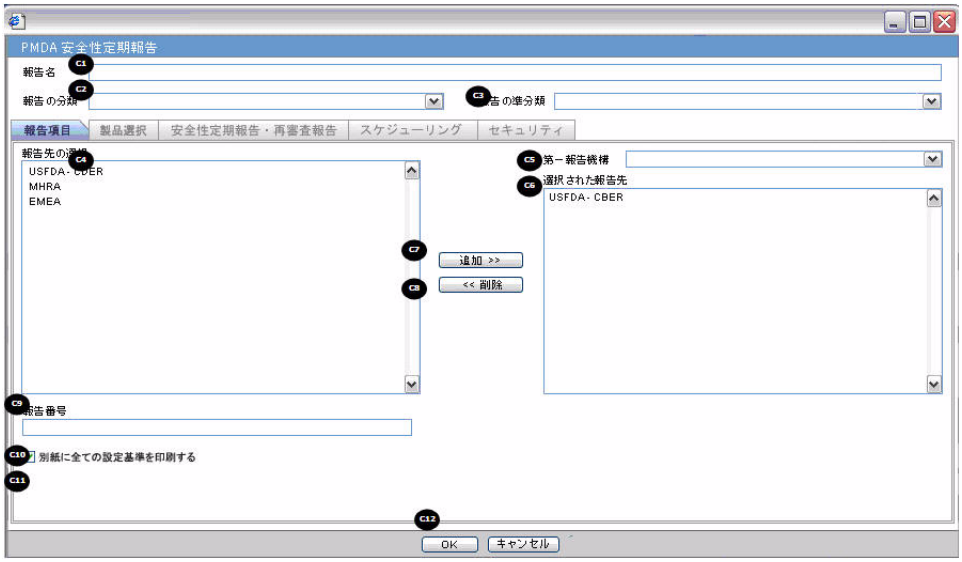
  The following message is displayed along with the above error:

  It is necessary to enter above information in order to save the configuration

- When **Modify**, **Copy**, **Delete**, or **Print** button is clicked without a selection of report, the following pop-up is displayed to select a report.

4.2.6.2 PSR /ReSD Details

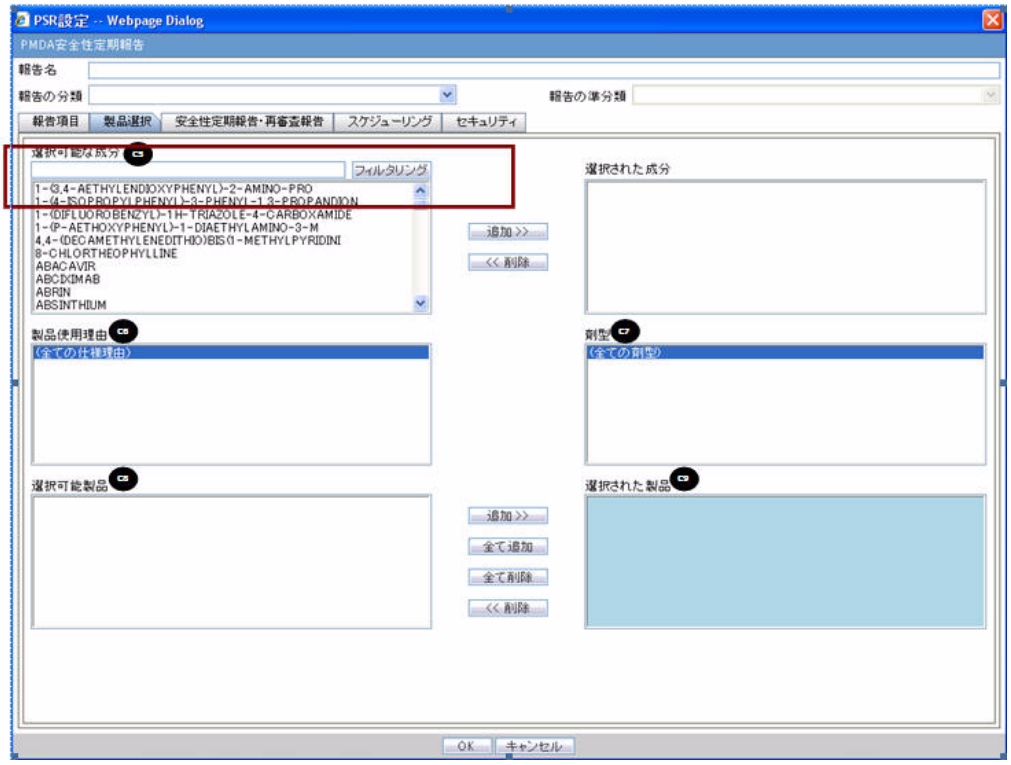
4.2.6.2.1 Subject of Report



#	Field Name	Description
	PMDA Periodic Safety Report	
	Subject of Report	
	Product Selection	
	PSR ReSD	
	Scheduling	
	Security	
1	Report Name	Manually Input a Name for the Report. It is displayed in the **Reports** > **PSR Reports** dialog box.
2	Report Category	Manually Input a Name for a Report Category. It is displayed in the **Reports** > **PSR Reports** dialog box.
3	Report Sub Category	
4	Selection of Reporting Destination	

#	Field Name	Description
5	Primary Report Agency	This list contains the Regulatory Authorities configured in **List Maintenance** > **Regulatory Authorities** (LM_REGULATORY_CONTACT table). If there is no Japanese Authority name configured, the English name is listed. The system allows you to select multiple agencies from the List of Agencies such that the report can be submitted to multiple agencies at the same time. The primary agency can be defined in this drop-down. When Japanese Message Profile is not configured in Console J for the selected Primary Agency, an error message is displayed as: Selected Primary Agency doesn't have configured Message Profile (I or J) in **Argus Console** > **Reporting Destination/EDI**. Once you click **OK**, the selection of the Primary Agency goes back to the previous selection. This check is executed when you try to go to the other tab, or click **OK** to save the configuration.
6	Selected Reporting Destination	
7	Add	
8	Delete	
9	Report Number	Manual entry text field that allows you to enter a report number.
10	Print all configuration criteria on separate cover page	Check box to print out the configuration of this report when the report is printed. When this is clicked, the Configuration page is printed at the beginning of the PSR/ReSD word print output. The page numbering of the PSR/ReSD does not include the Configuration page.
12	OK	
13	Cancel	

4.2.6.2.2 Product Selection



#	Field Name	Description
1	Available Ingredients	This list contains the Ingredients used for the products configuration. It is stored in the **LM_PF_INGREDIENT_J** table once a product has been configured. The system allows filtering the Ingredients within the available list of Ingredients by a entering the Ingredient name and clicking the **Filter** button. The search is performed in **Japanese ingredient name** only. If the name is blank, enter English ingredient name.
2	Filter	
3	Indication	This list contains the Indication configured for the product containing the ingredient in **C5** section. Use this to narrow down the products displayed in **C8**. The system allows to multi-select Indications using the standard Windows functionality of CTRL+CLICK. If Japanese name is not available, the English name is displayed.
4	Available Products	This list is auto-populated once the Ingredient has been selected and displays all products from the **LM_PRODUCT_J** table, containing the ingredient selected in **C5** section. The format is **Product name (Formulation, Concentration concatenated with the Concentration Units)**. If Japanese name is not available, the English name is displayed. The withdrawn products are displayed as well.

#	Field Name	Description
5	Selected Ingredients	When an ingredient has been selected, all products containing that ingredient are displayed in **Available Products** section. Multiple Ingredients can be selected at once to form a PSR product family.
6	Formulation	This list contains the formulation configured for the product using the ingredient in **C5** section (LM_ FORMULATION table). Use this to narrow down the products displayed in C8. The system allows to multi-select formulations using standard Windows functionality of CTRL+CLICK. If Japanese name is not available, the English name is displayed.
7	Selected Products	This list contains products that are selected from the **Available Products** list (C8). When at least one product is selected, the field has a blue background color. If the license is not withdrawn at the starting date of the PSR investigation timeframe, include the license in PSR and ReSD.
8	Add	
9	Remove	
10	Add All	
11	Remove All	
12	OK	
13	Cancel	
14	All Indications	
15	All Formulations	

Additional Information

- When no Japanese ingredients, indication, or formulation is configured in the Console, the English names are displayed.
- If the product is added or deleted in the **Product Selection** section before the PSR/ReSD status is marked as **Submitted**, it displays a warning pop-up:
  If the content of selected product is changed, IBD, JAD, and Assigned date can possibly be changed. Do you want to proceed?).
- If you add or delete the products in the **Product Selection** section before the first PSR report is marked as **Submitted**, it updates the IBD, Japan award date, and Assigned Date based on the new product set.
- When you copy an existing submitted PSR report, and JAD, IBD, Assigned dates are non-editable (you have not clicked the **RESET** button yet) and If you change the product selection, JAD, IBD and Assigned dates do not change. When this occurs, the following warning message is displayed:
  Because the configuration has the record of past investigation period, JAD, IBD, and Assigned Date for scheduling configuration will not be changed by modifying the Selected Products. It is necessary to use the **Reset** button and re-configure the investigation period if new PSR needs to be created based on modified product selection.

- All the forms printed as PSR and ReSD have only the information regarding the selected product in this configuration window.

4.2.6.2.3 Periodic Safety Report/ReSD

	Field Name	Description
1	Forms configuration	This field represents the main title of the UI.
2	Periodic Safety Report	This radio button is available to select either PSR or ReSD, so that you can create PSR and ReSD independently. This is selected as Default
3	Re-examination Submission Dossier	This radio button is available to select either PSR or ReSD, so that you can create PSR and ReSD independently.
	Data counting configuration	
4	Count Configuration	
5	Exclude events which don't meet the condition from the past data	When this is checked, the events that were reported in the past PSR, but do not meet the condition at the end of current investigational timeframe are subtracted Event was downgraded Report was nullified When this occurs, following message is printed under the first table of form 3: Among the Events that were count in the past report, there are nullified/became non-reportable during this investigational time frame. This is not checked by default.

	Field Name	Description
6	Exclude events which were reported by Paper report form	When this is checked, the events that were reported by Paper Form during the investigational time frame are excluded. This is not checked by default.
7	Exclude Incompletion report from output	When this is checked, the events reported as incompletion report during the investigational time frame are excluded. This is not checked by default
	PSR Report Form 3	
8	Form 3 Selection (Check box)	If this is checked, PSR Form3 is printed. This is checked by default.
9	Print Only the Term Preferred Term (Radio Button) Lower Level (Radio Button)	This field allows you to decide which term (PT or LLT) is to be printed on the form3. PT is selected by default.
a	Preferred Term (Radio Button)	
b	Lower Level (Radio Button)	
c	Print Only the term in (End of the sentence)	
10	Classify based on SOC	If this is checked, the **PSR Form 3 PT/LLT** section is grouped by SOC. In this case, the name of the SOC is listed at top of the section, and --- is used for separator between SOC and PT/LLT. Bold line is used for separating the groups. This is checked by default.
11	Print the report content as Case Listing in the separate paper	When this is checked, the case listing of the report content is printed out on a separate paper. All the configuration reflects the case listing. This is not checked by default.
	PSR Report FORM 4	
12	Form 4 Selection (Check box)	If this is checked, the PSR Form4 is printed. This is checked by default.
13	Print Only the Term	This field allows you to decide which term (PT or LLT)is to be printed on the form4. PT is selected by default.
a	Preferred Term (Radio Button)	
b	Lower Level (Radio Button)	
c	Print Only the term in (End of the sentence)	
14	Order SOC Alphabetically (Check box)	If this is checked, the SOC is printed in alphabetical order. If not checked, the SOC order is same as that of the MedDRA order. This is not checked as default.
	Non-Serious Unlisted PSR Report	

	Field Name	Description
15	Drug Non-Serious, Unlisted PSR	This field represents the title of the section.
16	Paper Report	Radio buttons:
	FD Report	When **Paper Report** is selected, Paper report format is generated.
		When **FD Report** is selected, CSV report format is generated.
		When FD report is selected, both 7-1 and 7-2 forms are checked in the checkboxes and these cannot be edited.
		Paper Report is selected by default.
	PSR Report FORM 7 - 1	
17	Form 7-1 Selection (Check box)	If this is checked, the PSR Form7-1 is printed.
		This is checked by default.
18	Print Blank Form	By checking this, the blank form is printed.
		This is not checked by default.
	PSR Report FORM 7 - 2	
19	Form 7-2 Selection (Check box)	If this is checked, the PSR Form7-2 is printed.
		This is checked by default.
20	Print the report content as Case Listing in the separate paper	When this is checked, the Case listing of the report content is printed out on a separate paper.
		This is not checked by default.
21	Separate Page Numbering (Check box)	When this is checked, the Page number is independent (starts from 1) for each form.
		This is checked by default.
40	Use Current Case Version	This radio button control is only displayed if DLP is enabled.
	Use DLP Case Version	**Use Current Case Version** is selected by default.
		Based on the PSR Configuration for DLP, the report is executed accordingly using latest Case Revision or using the DLP Case Revision.
	ReSD Report FORM 4	
22	Form 4 Selection (Check box)	If this is checked, the ReSD Form4 is printed.
		This is checked by default.
23	Print Only the Term	Allows you to decide which term (PT or LLT) you want to print on form4.
	Preferred Term (Radio Button)	PT is selected by default.
	Lower Level (Radio Button)	
a	Preferred Term (Radio Button)	
b	Lower Level (Radio Button)	
c	Print Only the term in (End of the sentence)	

	Field Name	Description
24	Classify based on SOC	If this is checked, the **PSR Form 3 PT/LLT** section is grouped by SOC. In this case, the name of the SOC is listed at the top of the section, and --- is used as separator between SOC and PT/LLT. Bold line is used for separating the groups. This is checked by default.
25	Print the report content as Case Listing in the separate paper	When this is checked, Case Listing of the report content is printed out on a separate paper. This is NOT checked by default.
	ReSD Report FORM 5	
26	Form 5 Selection (Check box)	If this is checked, the ReSD Form5 is printed. This is checked by default.
27	Print Only the Term	Allows you to decide which term (PT or LLT) is to be printed on form4. PT is selected by default.
a	Preferred Term (Radio Button)	
b	Lower Level (Radio Button)	
c	Print Only the term in (End of the sentence)	
28	Order SOC Alphabetically (Check box)	If this is checked, the SOC is printed in alphabetical order. If this is not checked, the SOC order is same as that of the MedDRA order. This is not checked by default.
	ReSD Report FORM 7	
29	Form 7 Selection (Check box)	If this is checked, the ReSD Form 7 is printed. This is checked as default.
	ReSD Report FORM 8	
30	Form 8 Selection (Check box)	If this is checked, the ReSD Form 8 is printed. This is checked by default.
	ReSD Report FORM 9	
31	Form 9 Selection (Check box)	If this is checked, the ReSD Form 9 is printed. This is checked by default.
	ReSD Report Tabulations	
32	Tabulations	If this is checked, all the tabulations in the section are checked and included in the print. This is checked by default.
33	Tabulation for Unlisted Events	When checked, this tabulation is included in the print. This is checked by default.
34	Tabulation for Listed Events	When checked, this tabulation is included in the print. This is checked by default.

	Field Name	Description
35	Case Overview Tabulations	When checked, this tabulation is included in the print. This is checked by default.
36	Overdose Tabulation	When checked, this tabulation is included in the print. This is checked by default.
37	Accident Exposure Tabulation	When checked, this tabulation is included in the print. This is checked by default.
38	OK	
39	Cancel	

Additional Information

- Separate page numbering always follow the previous form of PSR and ReSD. The following is the order of the page numbering sequence:

  PSR Form 3 , 4, 7, 7-2, ReSD Form 4, 5, and 789

- When you select **PSR**, **ReSD** using the radio button, the system selects all the forms available for each set of report automatically (PSR - above table 1, 7, 10, and 13) (ReSD - above table 15, 20, 23, 25, 27, and 29). By default, PSR is selected and PSR forms are selected.
- If the radio button is used to select the PSR form, the previously checked forms on the ReSD are unchecked. If the radio button is used to select the ReSD form, the previously checked forms on PSR are unchecked. While the PSR is selected, the **ReSD** section is disabled. While ReSD is selected, **PSR** section is disabled.
- If you close the configuration and opens again, the configuration on the UI remains as it was at the time of the last operation.
- All the forms format are based on the Novartis PSR form sample.
- You are not allowed to change the configuration parameters for PSR Form 3, 4 and ReSD Form 4, 5; if there are any past (non-editable) timeframe rows. If there are past timeframe rows in the scheduling frequency table, configuration of the PSR Form 3, 4 and ReSD form 4, 5 is non-editable.
- When you check the **Print the report content as Case Listing in the separate paper**, the Case Line Listing along with the report content is printed on a separate paper.
  - The Case Listing is printed only for the current timeframe for PSR form 3, ReSD Form 4 and PSR Form 7-2.
  - This line listing is independently printed (using separate page) regardless of the **Configuration Printing** check box status. If you checked the option to print out the configuration content and Case Listing, the Case Listing is appended after the configuration content.
  - The order of the print is **Configuration** > **Form 3 Line Listing** > **Form 7-2 Line Listing** > **All the actual reports**
  - The Case Line Listing report does not follow the **Separate Page** option. The Case Line listing is always separated and starting from page 1 for each form.

PSR Form 3 Case Line Listing

#	Field Name	Description
1	PSR/ReSD Case Line Listing	This field represents the section title.
2	Periodic Safety Report	This field represents the 2nd title.
3	Periodic Safety Report form #3	This field represents the title for **Form 3** section.
4	Types of adverse event	The List of AEs are printed using exactly the same rule and order as that of the PSR Form 3.
5	Case Number	All the reported AE's case numbers are printed in this field. These case numbers are separated by comma.
6	Number of AEs reported during this timeframe	Number of the AEs available also on the PSR form 3 for this report's investigational timeframe.

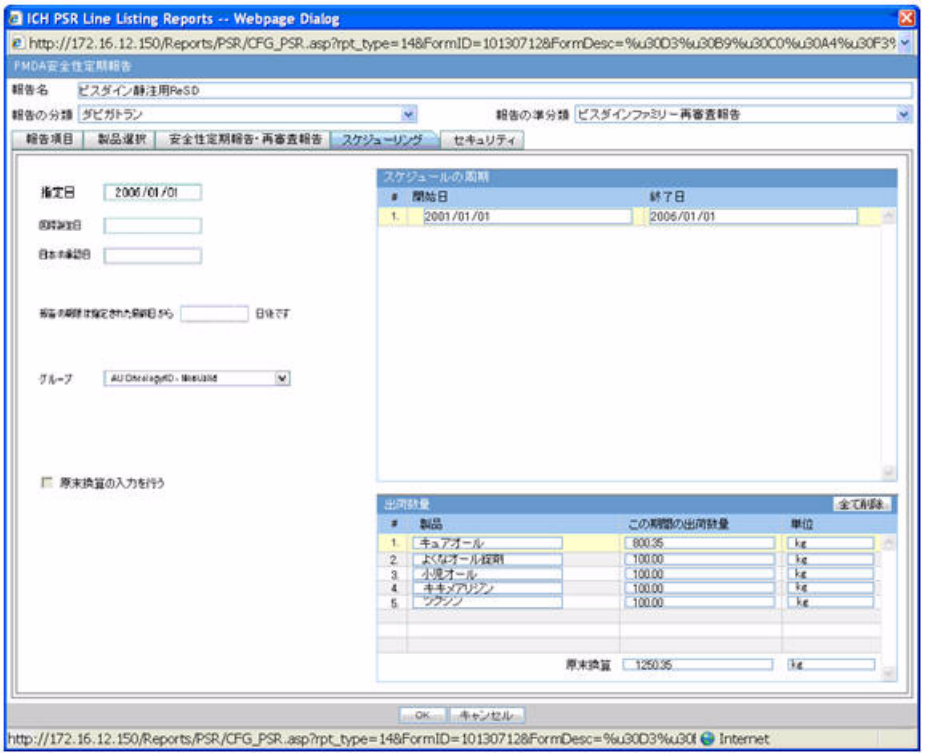
PSR Form 7 Case Line Listing

#	Field Name	Description
1	PSR/ReSD Case Line Listing	This field represents the section title.
2	Non Serious, Unlisted Periodic Safety Report	This field represents the 2nd title.
3	List of non-serious, Unlisted adverse event	This field represents the title for **Form 7-2** section.
4	(form 7 body)	This section is always same as the PSR form 7.
5	Case Number	The Argus case numbers are added using this field.

ReSD Form 4 Case Line Listing

#	Field Name	Description
1	PSR/ReSD Case Line Listing	This field represents the section title.
2	Re-examination submission dossier	This field represents the 2nd title.
3	ReSD Form #4	This field represents the title for **Form 4** section.
4	Types of adverse event	List of AEs are printed using exactly the same rule and order as that of PSR Form 3
5	Case Number	All the reported AE's case numbers are printed in this field. These case numbers are separated by comma.
6	Number of AEs reported during this timeframe	Number of the AEs available also on the ReSD form 4 for this report's investigational timeframe.

4.2.6.2.4 Scheduling

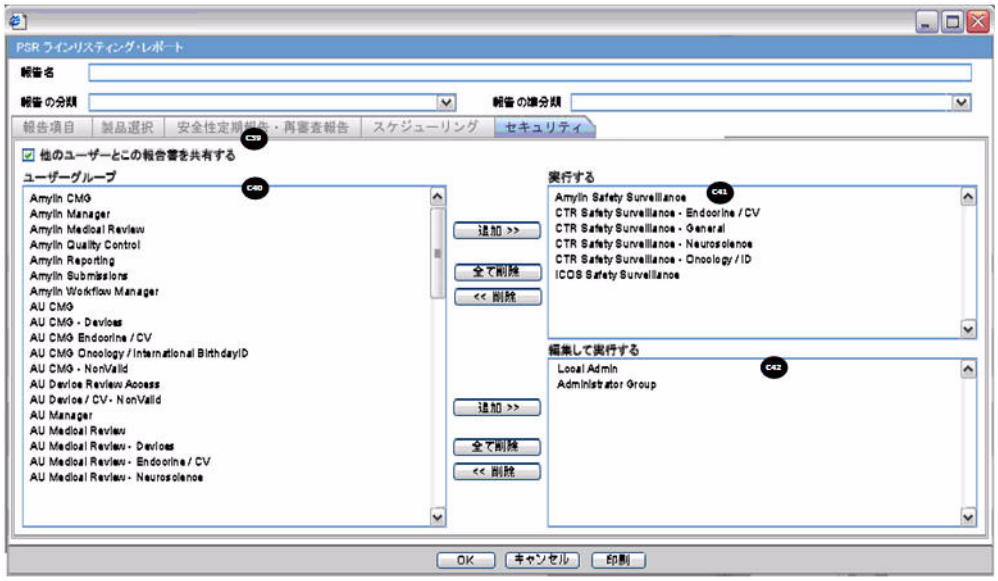


#	Field Name	Description
1	Scheduling	
2	Assigned Date	

#	Field Name	Description
3	International Birthdate	
4	Japanese Award Date	
5	Report is due ___days after specified end date	
6	Group	
7	Frequency of the schedule	
8	Start Date	
9	End Date	
10	Add	
11	Delete	
12	Reset	
13	#	
14	Delivery quantity	This field represents the title of the section. This section displays the delivery quantity information for each timeframe row, when that row is clicked.
15	Clear All	When you click this button, all the entered information on this UI is cleared (The data entered by you only. For example, the Delivery Quantity and Delivery Unit for all the products in the **Delivery Quantity** section is removed but the product names remain in each row. When this is clicked, a confirmation window with the following message is displayed: If you continue, the entered information is erased. Do you want to continue?. The content in the UI is deleted when you enter **OK**. No actions are taken on the table if you select **Cancel** in the message window.
16	Products	Product names used in this PSR appear as default. The names can be changed only at first report generation. From second report, names are read-only unless they are newly added. The maximum text length is 70.
17	Delivery quantity during this period	This field represents the text entry for numbers. The maximum text length is 12 (including the decimal point and number). Only numeric character and decimal point are allowed.
18	Unit	Type ahead functionality with console J Unit (J). For the units data that does not have unit(J), if unit (J) is not available, the field is left blank. You can change the unit only at first report generation.

#	Field Name	Description
19	Total Amount	Text entry for number. Only when the entered units are the same, the calculated total from above is displayed in this field. Maximum text length is 15 (including the decimal point and number). Only numeric character and decimal point are allowed.
20	Entering the Delivery Quantity	Delivery quantity table is entered into the report only when this is checked. This is unchecked by default. If this is not checked, the **Delivery** section of the report is blank (unchecking does not delete the values in UI).

4.2.6.2.5 Security



#	Field Name	Description
1	Share this report with other users	
2	User Groups	
3	Add	
4	Remove All	
5	Remove	
6	Execute	
7	Modify & Execute	
8	OK	
9	Cancel	

4.2.6.2.6 Printing PSR / ReSD

#	Field Name	Description
1	Report Batch Printing	
2	Run at	You can specify the time of Reporting using this field. The date entry is in Japanese.
3	Run Now	This field represents the Print now option.
4	Print As	You can select printing option from Final, Draft, Internal, or Other.
5	Final	
6	Draft	
7	Internal	
8	Other	
9	Due Date	Automatically populate the calculated value by using the due days.
10	OK	
11	Cancel	

Generating the Document

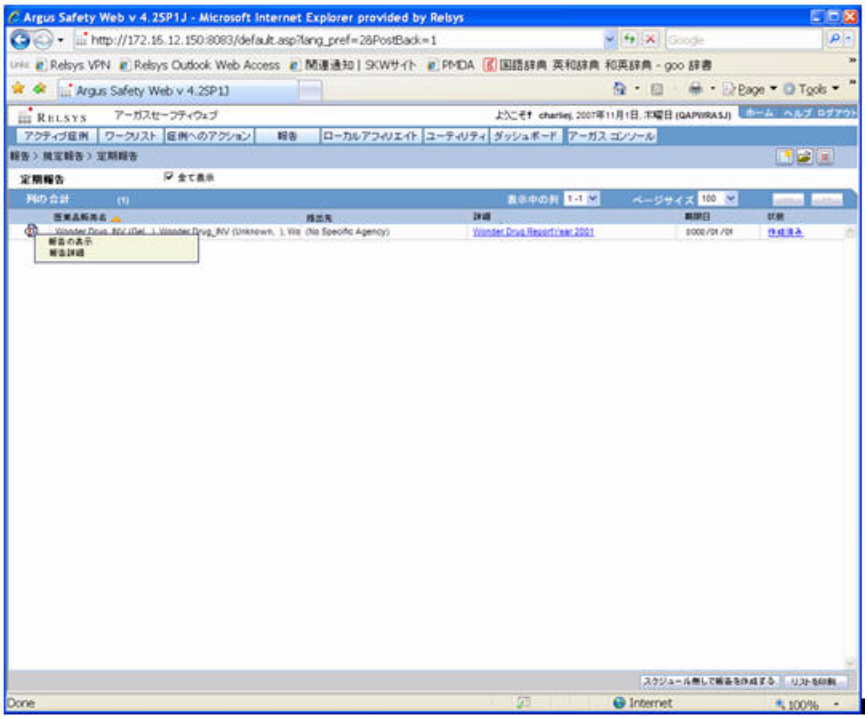
Generation of the document is executed using the following process:

1. Click **View Report** in the **Reports** > **Compliance** > **Periodic Reports.**
2. Check-out the report from the **View and edit PSR/ReSD** pop-up.
3. Edit the checked-out word document
4. Check-in using the same **View and edit PSR/ReSD** pop-up.
5. Publish the PDF file (converting from the checked-in word doc)

Printing Requirements

- The system allows you to Print the Report and update the Report output in the Word document.
- The change of the configuration for the same investigation timeframe can be done multiple times only before the status is changed to **Submitted**. The changes in the configuration after the **Submitted** status of the PSR is applied on the next investigational time period.
- From the **Reports** > **Compliance** > **Periodic Reports,** selecting **View Report** allows you to View the PSR/ReSD Report in Word document to upload the report.

– When the J user opens **Reports** > **Compliance** > **Periodic Reports** from the menu, the Japanese UI is displayed for Periodic report list. The pop-ups for the PSR View and Edit are Japanese.



#	Field Name	Description
1	PERIODIC REPORTS	
2	View All	
3	Total Number of Rows (1)	
4	Displaying Rows	
5	Page Size	
6	Trade Name	The J UI displays available Japanese data. When Japanese data is not available, the English data is displayed. The **Trade Name** section displays the multiple trade names using comma separated list of the selected products. The Trade Name displays the original product selected: English or Japanese. If PSUR was created for the English product names, the English product name is used in the list. If the PSR is created with the Japanese product names, the Japanese product name is used in the list. If the selected product in the PSR does not have the Japanese Trade name, the English trade name is displayed for that PSR.
7	Destination	The Japanese UI displays the available Japanese data. When Japanese data is not available, the English data is displayed. When Destination is not available, display **No specific receiver**.

#	Field Name	Description
8	Description	The Japanese UI displays the available Japanese data. When Japanese data is not available, the English data is displayed.
9	Due Date	English date format is **DD-MMM-YYYY**. Japanese date format is **YYYY/MM/DD**
10	Status	Status appears in Japanese in the Japanese UI, and in English in English UI and can have the following possible values: Deleted Scheduled Generated Approved Disapproved Submitted New Data Available No Longer Required
11	Create Unscheduled Report	
12	Print List	
13	View Report	
14	Report Details	

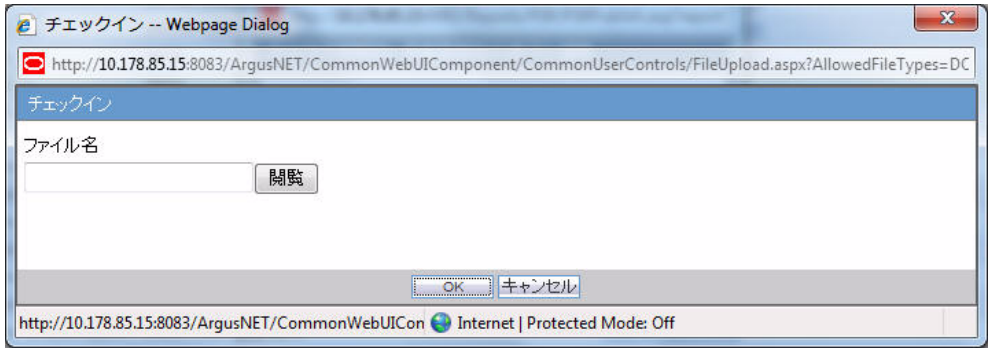
- The report output is in Word Document. This works in the similar way as ePSUR publishing where you are allowed to edit the Word output outside the system and once generated, can publish the FINAL Word Document.
  - When the report is generated and never checked out, the center button display **Check-out** to let you revise the document. At this time, **Publish** button is disabled.
  - Check-out can be executed by one user only. Other users cannot check in the checked-out files.
  - Once the check-out is executed, the **Check-out** button is changed to the **Check-in** button. This button is used to check-in the revised checkout file.
  - When the file is checked-in, the center button is changes to the **Check-out** button.
  - When the file is not checked-out or not published, you can check-in/check-out the file as many times as you want.
  - When the file is not checked-out or not published, the group which has the access rights to this report can execute the check-in, check-out, and publish.
  - The **View** button is always enabled (regardless of the check in/check out status). It displays the latest updated Word document or the PDF after final Publish.
  - The **Publish** button is enabled after at least one time of the check-in action. The **Publish** button is disabled when the document is checked-out.
  - Once the final Word file is created, the Word document is saved in the repository. All the past PSR word output are saved. When you update the

Word document and uploads it, the system overwrites the automatically generated document in the database.

- Once the **Publish** button is executed and the PDF file is created, the **Check-Out** button is grayed out and disabled.
- Once the document is checked-in, the **Check-in** button is changed to **Check-out**, and the **Publish** button is enabled to publish the PDF report from the Word document.
- The **Publish** button converts the checked-in Word document to the PDF file.
- Once **Publish** is done, the Word document is no longer available. The **Check-in / Check-out** button is disabled only when the PSR is published and the label is changed to **Check-out**.

#	Field Name	Description
1	View and edit PSR/ReSD	
2	Select necessary action	
3	Checkout	
4	Checkin	
5	View	
6	Publish	
7	Close	

- When the **Check-in** button is clicked, the following pop-up is displayed to specify the file name. This can be done by either specifying the file name in the text box, or selecting the location using the **Browse** button.

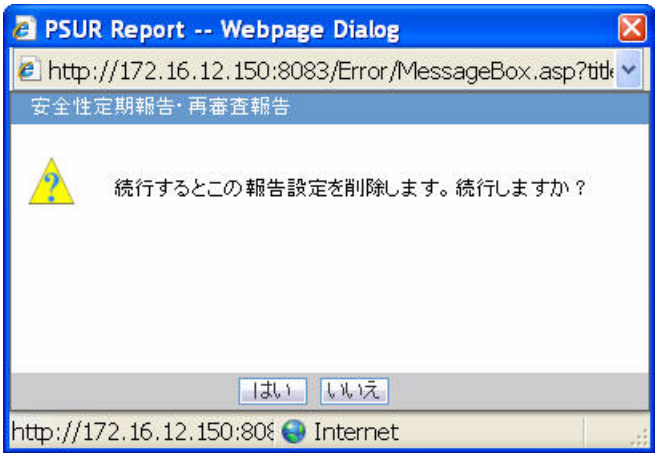


#	Field Name	Description
1	Checkin	
2	File Name	

#	Field Name	Description
3	Browse	
4	OK	
5	Cancel	

- If the data is changed manually in the Word document, this change is not applied to the next report. The report needs to be changed again.
- The configuration of the PSR/ReSD can be edited while the PSR is checked-out. The change is affected only when the PSR is created again.

4.2.6.2.7 Deleting PSR / ReSD



#	Field Name	Description
1	PSR/ReSD	
2	Are you sure you want to remove this report configuration?	
3	Yes	
	No	

4.2.7 Clinical Study Periodic Safety Report

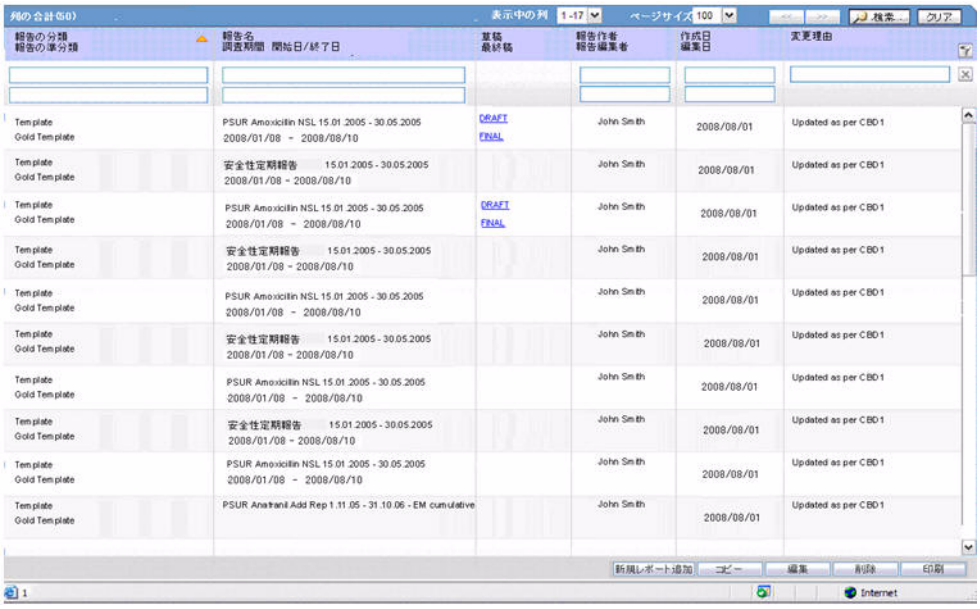
4.2.7.1 Format

The system allows configure and output Clinical Study Periodic Reports defined by the PMDA for products. The purpose is to define a fixed set of Clinical Study Periodic Safety Reports (CSPSR) for PRIMARY AGENCY (the various regulatory authorities as optional) and then associate products with these reports. The CSPSR can then be scheduled automatically.

The CSPSR applies only for Japanese licenses.

Argus J is capable of output CSPSR Cover and Line Listing form.

- The system contains a configuration screen to define a CSPSR report. A new menu item, **Reports** > **Periodic Reports** > **Clinical Study Periodic Safety Report**) has been created. When this is clicked, the following page is displayed.



Field Name	Description
Category	
Sub Category	
Report Name	
Inclusion Start Date / Stop Date	
DRAFT / FINAL	
Author Created	
Author Modified	
Date Created	
Date Modified	
Justification	
Search	
Clear	
Total Number of Rows ( )	
Displaying Rows	
Page Size	
New Report	
Copy	
Modify	
Delete	
Print	

CSPSR Main Window

- If the report is being currently opened by another user for modification, the system displays the following message:
  The report which is selected is being used by XXXX and cannot be modified.
  where XXX is the full user name of the user who has it opened.
- The **Create from Template** button that is available on **Argus E PSUR and CTPR** section, is not added for Japanese PSR, CSPSR configuration.
- This page displays a list of the CSPSR reports stored in the system.
  - You can add a new report by clicking the **New Report** button.
  - The **Copy** button creates a copy of an existing report.

    When you copy an existing CSPSR Report, all the configuration of the report including timeframe rows are also copied.

    The Report Name of the new copy has **Copy of** in front of the name.

    When the configuration of already Submitted report is copied, the past dates in the schedule frequency, Clinical Study Plan Submit Date, Clinical Trial for Partial Change Submit Date, and Assigned date are also copied as read-only. Other sections of the copied configuration are editable.

    When you copy an existing non-submitted CSPSR report, all the configuration including timeframe rows is also copied. As the original report was non-submitted, all the timeframe rows are retained as non-editable or editable as they were in the original CSPSR. The CSPSD, CTPCSD, and Assigned Date becomes editable or non-editable depending upon if there are timeframe rows in the copied CSPSR which are non-editable.
  - The **Modify** button displays the report definition.
  - The **Delete** button allows you to delete a report after displaying the following confirmation message:
    Proceeding to Yes will remove the report configuration. Proceed?.
  - Clicking **Print** results in displaying a new dialog box prior to Report Preview allowing you to select from several preview or direct export options: Word output.
- The **Delete** option is only available if there are no Final Reports generated for the Periodic Reports. In any case, the **Delete** option only hides the report from the list.
- The generated last executed report is available from a link that fetches the report from the database.
- Clicking **New** or **Modify** displays the **CSPSR Configuration** Window.
- Once the state of the report is changed to **Submitted**, you are not able to update the configuration of that CSPSR. This is achieved by disabling the **OK** button. For example, when the state is un-submitted, the report is editable again. In addition, when the non-editable configuration is opened, the following warning message is displayed:
  This configuration is not modifiable because the status of this Clinical Study Periodic Report is Submitted.
  When you click **OK**, the Configuration window is displayed. When you click **Cancel**, the Configuration window is not displayed.
- When the status of the report is **Submitted**, only the Configuration page is printed.

- Copy can be done any time while the configuration exists.

  When you create CSPSR after 2nd time, the new copy of the configuration is required. You can then modify the content to print the current CSPSR.

- Before saving the CSPSR configuration, Report Name, Primary Agency, Product Selection, and at least one timeframe need to have a value entered.

  Else, the following error messages are displayed:

  When Report Name is not entered:

  Report Name is not entered

  When Primary Agency is not entered:

  Primary Agency is not entered

  When selected product is not available:

  Product is not selected

  When atleast one time frame is not entered:

  Investigation time frame is not configured

  Following message is displayed along with the above error:

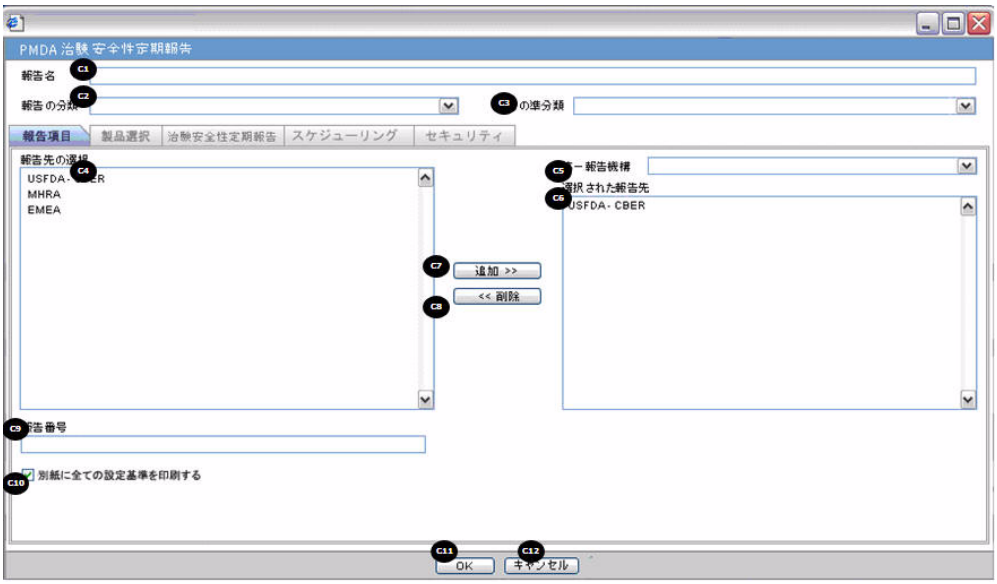
  It is necessary to enter above information in order to save the configuration

- When the **Modify**, **Copy**, **Delete**, or **Print** button is clicked without a selection of report, the following pop-up is displayed to select a report.

- If any one Submitted report is present, the Report Configuration is non-editable even if it has multiple generated reports with different states.

4.2.7.2 CSPSR Details

4.2.7.2.1 Subject of Report

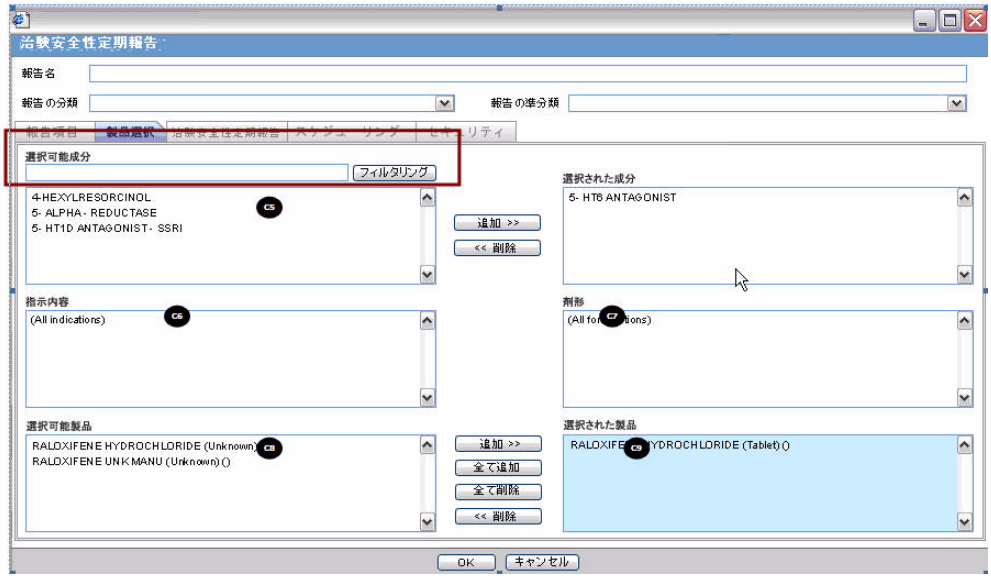


#	Field Name	Description
	PMDA Periodic Safety Report	
	Subject of Report	
	Product Selection	
	CSPSR	
	Scheduling	
	Security	
1	Report Name	Manually Input a name for the report that is displayed in the **Reports** > **CSPSR Reports** dialog box.
2	Report Category	Manually Input a name for a Report Category that is displayed in the **Reports** > **CSPSR Reports** dialog box.
3	Report Sub Category	
4	Selection of Reporting Destination	

#	Field Name	Description
5	Primary Report Agency	This list contains the Regulatory Authorities configured in **List Maintenance** > **Regulatory Authorities** (LM_REGULATORY_CONTACT table). If there is no Japanese Authority name configured, the English name is listed. The system allows you to select multiple agencies from the List of Agencies so that the report can be submitted to multiple agencies at the same time. The primary agency can be defined in this drop-down list. When Japanese Message Profile is not configured in Console J for the selected Primary Agency, the following error message is displayed: Selected Primary Agency doesn't have configured Message Profile (I or J) in Argus Console/Reporting Destination/EDI. Once you click **OK**, the selection of the Primary Agency goes back to the previous selection. This check is executed when you try to go to the other tab, or click **OK** to save the configuration.
6	Selected Reporting Destination	
7	Add	
8	Delete	
9	Report Number	Manual entry text field that allows you to enter a report number.
10	Print all configuration criteria on separate cover page	This field represents the check box to print the configuration of this report when the report is printed. When this is clicked, the Configuration page is printed at the beginning of the CSPSR Word print output. The page numbering of the CSPSR does not include the Configuration page.
12	OK	
13	Cancel	

If the Japanese Agency Name is not configured in the Console, the English name is displayed on the screen for that agency.

4.2.7.2.2 Product Selection



#	Field Name	Description
1	Available Ingredients	The system allows filtering the Ingredients within the available list of Ingredients by entering the Ingredient Name and clicking the **Filter** button. The search is performed in **Japanese ingredient name** only. If the name is blank, then enter English ingredient name.
2	Filter	
3	Indication	This list contains the Indication configured for the product containing the ingredient in **C5** section. Use this to narrow down the products displayed in **C8**. The system allows to multi-select Indications using standard Windows functionality of CTRL+CLICK. If Japanese name is not available, display the English name
4	Available Products	This list is auto-populated once the Ingredient has been selected and displays all products from **LM_ PRODUCT_J** table, containing the ingredient selected in **C5** section. The format is **Product name (Formulation, Concentration concatenated with the Concentration Units)**. If the Japanese name is not available, the English name is displayed. The withdrawn products are displayed as well.
5	Selected Ingredients	This list contains the Ingredients used for the Products Configuration. It is stored in the **LM_PF_ INGREDIENT_J** table once a product has been configured. When an ingredient has been selected, all products containing that ingredient are displayed in **Available products** (C8) section. Multiple Ingredients can be selected at once to form a CSPSR product family.

#	Field Name	Description
6	Formulation	This list contains the formulation configured for the product using the ingredient in **C5** section (LM_ FORMULATION table). Use this to narrow down the products displayed in **C8**. The system allows to multi-select formulations using standard Windows functionality of **CTRL+CLICK**. If Japanese name is not available, the English name is displayed.
7	Selected Products	This list contains products that are selected from the **Available Products** list (C8). When at least one product is selected, the field has a blue background color. If the license is not withdrawn at the starting date of the CSPSR investigation timeframe, include the license in CSPSR. **Data Entry Discipline**: When the new product is available because the new product with the same ingredient released in the CSPSR, you need to manually set up the new configuration. When no Japanese ingredients, indication, or formulation is configured in the Console, the English names are displayed. When you copy an existing submitted CSPSR report, and CSPSD, CTPCSD, the Assigned dates are non-editable (you have not clicked the **RESET** button yet). In such a scenario, if you change the product selection, CSPSD, and CTPCSD, the Assigned dates do not change. When this scenario occurs, the following warning message is displayed: Because the configuration has the record of past investigation period, CSPSD, CTPCSD, and Assigned Date for scheduling configuration is not changed by modifying the Selected Products. It is necessary to use the **Reset** button and re-configure the investigation period if new CSPSR needs to be created based on modified product selection. All the forms printed as CSPSR have only the information regarding the selected product in this Configuration window. When a product is moved to **Selected Products** field, but this does not have the Clinical Compound Number, the following error message is displayed: Selected product doesn't have a Clinical Compound Number. It is necessary that the study product license has at least one Clinical Compound Number in order to include in the report.

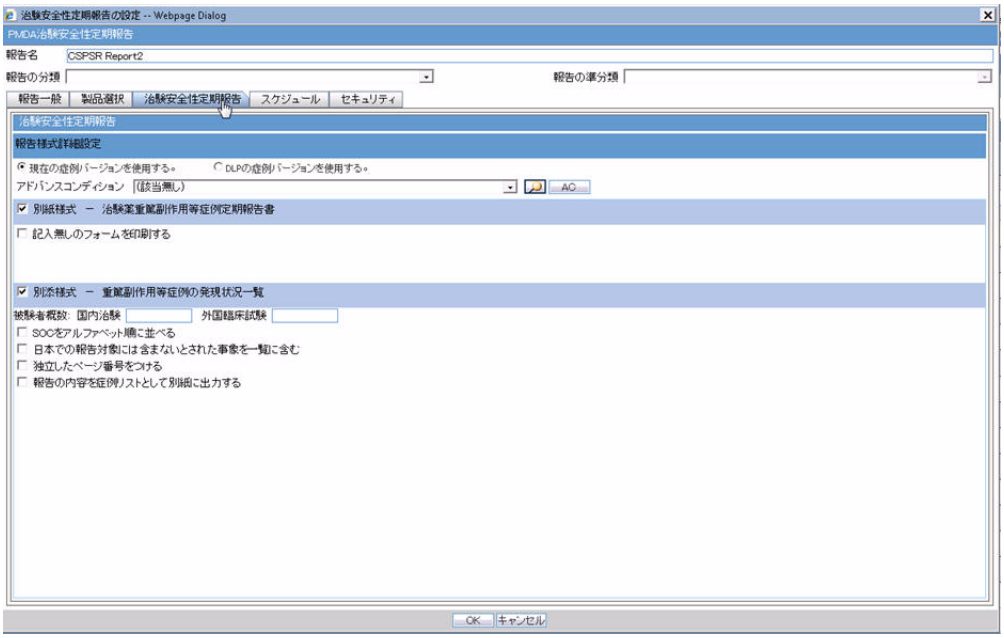
#	Field Name	Description
		When a product is moved to the **Selected Products** field, but this does not have matching Study, the following warning message is displayed: Studies that have the selected product's Clinical Compound Number doesn't exist. Do you want to include the product in the report?. If you select **Yes**, this product is populated in the **Selected Products** field.
8	Add	
9	Remove	
10	Add All	
11	Remove All	
12	OK	
13	Cancel	
14	All Indications	
15	All Formulations	
16	Available Domestic Studies	
17	Selected Domestic Studies	
18	Available Foreign Studies	
19	Selected Foreign Studies	

Available/Selected Domestic/Foreign Studies multi-select shuttle controls

- Available Domestic Studies field dynamically lists all the company configured studies in Console, which consists of the selected CSPSR products and have country configured as **Japan**. The **Study ID (J)** value from **Console** > **Study Configuration** must be listed.
- Available Foreign Studies field dynamically lists all the distinct (case-sensitive) studies from foreign (non-Japan) cases, which consist of the selected CSPSR products. The **Study ID (English)** value is displayed from **Case Form** > **General** Tab > **Study Information** section. If **Study ID (English)** is not available, the **Study ID (J)** value must be displayed.
- These 2 shuttle controls have **Add**, **Add All**, **Remove**, and **Remove All** buttons to Select/Remove studies between **Available and Selected Domestic/Foreign Studies** fields.
- If any product is added/removed from the **Selected Product** field, the **Available and Selected Domestic/Foreign Studies** fields are also updated dynamically.
- The **Selected Domestic and Foreign Studies** field is displayed in blue background, same as that of the **Selected Products** fields.
- If Selected Domestic Studies fields do not contain any study, clicking on **OK** button displays the following error message and brings the focus back on the **Selected Domestic Studies** field:

  At least one domestic study must be selected in order to proceed with the configuration

4.2.7.2.3 Clinical Study Periodic Safety Report



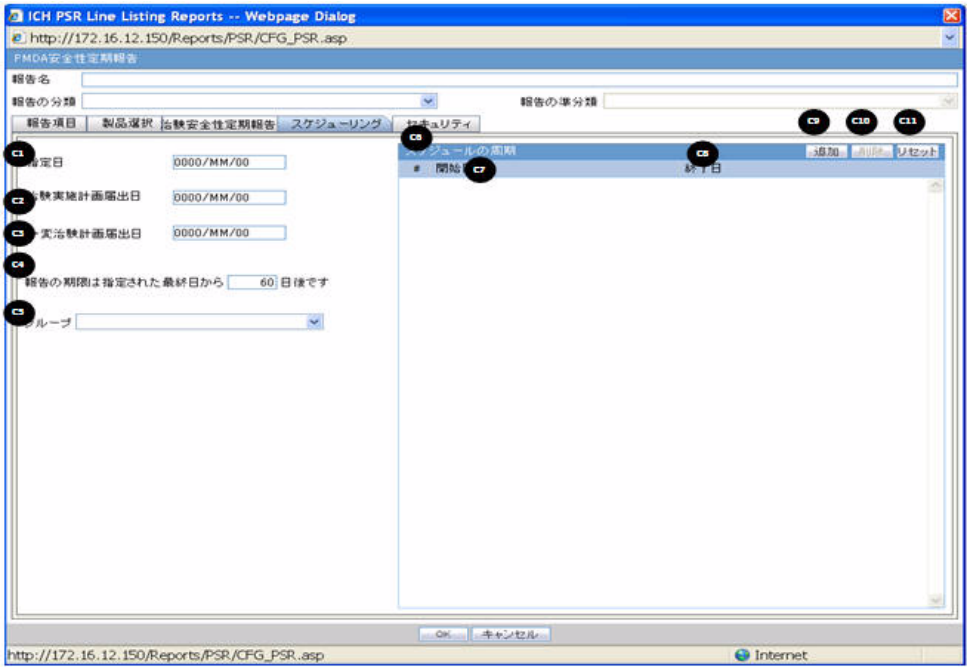
#	Field Name	Description
1	Forms configuration	This field represents the main title of the UI.
2	Clinical Study Periodic Safety Report	This field represents the title of the set of configuration forms.
	CSPSR Cover	
3	Report form - Clinical Study Serious AE Case Periodic Report	This field represents the title of the form to be configured.
4	Print Blank Form	This checkbox is used to print the blank form.
	CSPSR Line Listing	
5	Report form - Serious AE Case Occurrence Status Listing	This field represents the title of the form to be configured.
6	Number of subject: Domestic Study___ Foreign Study___	This is a manual data entry (Numeric only) field. You can enter total number of subject for this entire clinical study for domestic and foreign. The Maximum digits for this number is 7 for both fields.
7	Order SOC Alphabetically (Check box)	If this is checked, the SOC is printed in alphabetical order (alphabetically based on their English names). If not checked, the SOC order is same as that of the MedDRA order.
8	Include foreign AE marked as "Not include for the report in Japan" (Check box)	When this is checked, the system includes AEs in the foreign cases that have flags for **Not include for the report in Japan** (available in the **Case Form** > **Event** tab)

#	Field Name	Description
9	Use Current Case Version Use DLP Case Version	This radio button control is only displayed if DLP is enabled. Use Current Case Version is selected by default. Based on the CSPSR configuration for DLP, the report is executed accordingly using latest case revision or using the DLP case revision.
10	Separate Page Numbering (Check box) **Note**: When separate page numbering is not used, it always follows the previous form of CSPSR. Order of the page numbering sequence is following: CSPSR Form Cover, Line Listing	When this is checked, the page number becomes independent (starts from 1) for CSPSR Line Listing.
11	Print the content of the report as case listing on separate page	If this is checked, Case Listing of the CSPSR Line Listing content is printed on a separate page. **Note:** The Case Listing is printed after the configuration content, and using following style guide template for listing.
12	OK	
13	Cancel	

StyleGuide_CaseList.doc

#	Field Name	Description
1	Periodic Safety Report - Case Line List	Static text
2	Clinical Study Serious Event Case Periodic Report	Static text
3	Serious AE, etc. Case Occurrence Status Line Listing	Static text
4	AE, etc. Case classification	Static text
5	AE, etc. Case Count	Static text
6	This investigation period	This column has the same output as the printed CSPSR
7	Cumulative Total	This column has the same output as the printed CSPSR
8	Case Number	Case Numbers that have counted events are listed with the comma used as a separator.
9	Domestic Clinical Study	Static text. This section only considers the cases, which contain the studies configured as **Selected Domestic Studies** in the **Product Selection** tab.
10	SOC	This field has the same output as the printed CSPSR. The Case Listing is not printed for this section.
11	Event sectopm	This field has the same output as the printed CSPSR. The Case listing is printed for this section.
12	Foreign Clinical Study	Static text. This section only considers the cases, which contain the studies configured as **Selected Foreign Studies** in the **Product Selection** tab.
13	Foreign Marketed Spontaneous Report, etc.	Static text.
14	This investigation time frame: YYYY?MM?DD????YYYY?MM?DD? - TBD	This field has the same output as the printed CSPSR.
15	Terms for AE: MedDRA/J version ( ) was used.	This field has the same output as the printed CSPSR.

4.2.7.2.4 Scheduling



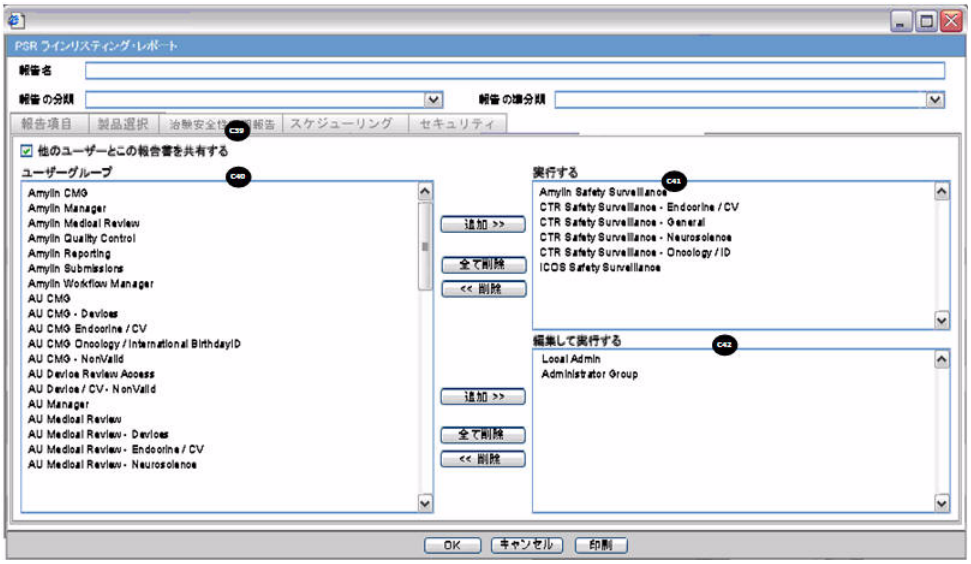
#	Field Name	Description
1	Assigned Date	This field is automatically populated based on the calculation using the following rule (Editable field): Whenever you enter/change **Clinical Study Plan Submit Date** field or **Clinical Trial for Partial Change Plan Submit Date** field, the Assigned date is recalculated automatically and the correct date is populated based on the change. This date is populated to the **Frequency of the schedule** table on the right side of the UI as the first CSPSR start date. The first start date is editable in the table. When the first report is not yet marked as **Submitted**, and if you manually change the Assigned date, Start date of the first period of the CSPSR in the **Frequency of Schedule** window is automatically re-populated with this Assigned date. When the Assigned date is changed manually on a copy of an existing submitted CSPSR and you have removed all the previous periods using the **RESET** button, the Assigned date can be modified. When this happens, the first start date of the CSPSR is populated in the **Frequency of Schedule** window, with the new updated Assigned date. When you try to change the Assigned date manually to a different date, the following pop-up message is displayed: Assigned date is different from the date expected from CSPSD and CTPCSD. Do you accept the change. If **OK** is clicked, the new value remains in the field. If **Cancel** is clicked, the original value is replaced with the entered value in the field.

#	Field Name	Description
2	Clinical Study Plan Submit Date	This is a manual data entry text field. It is an editable text field. If this field is changed and it is later than the **Clinical Trial for Partial Change Plan Submit Date**, the following error message is displayed: If CSPSD is changed, Assigned date will be changed. Do you want to proceed? If **OK** is clicked, the new value remains in the field. If **Cancel** is clicked, the original value is replaced with the entered value in the field. CSPSD is an editable field, if the CSPSR is not in Submitted state and it does not have any previous non-editable timeframes. Once a CSPSR is marked as **Submitted**, this field becomes non-editable.
3	Clinical Trial for Partial Change Plan Submit Date	This is a manual data entry text field. This is an editable text field. If the CTPCSD is changed and this date is earlier than the CSPSD, the following error message is displayed: CTPCSD cannot be earlier than CSPSD. If the CTPCSD is changed, the following warning message is displayed: If CTPCSD is changed, Assigned date will be changed. Do you want to proceed? If **OK** is clicked, the new value remains in the field. If **Cancel** is clicked, the original value is replaced with the entered value in the field. If the CSPSR is not in **Submitted** state and it does not have any previous non-editable timeframes, CTPCSD is an editable field. Once a CSPSR is marked as **Submitted**, this field becomes non-editable.
4	Report is due ___days after specified end date	This option allows you to specify the due date of the CSPSR, xx days after the end date specified for the scheduling period. The value entered in this field is added to the current end date and displayed in the printing UI as due date.
5	Group	This option allows you to specify which Argus group is responsible for the Periodic report, once scheduled by the application. The report appears on the designated group's worklist for Reports.
6	Frequency of the schedule	

#	Field Name	Description
7	Start Date	This field is a date entry field for the reporting timeframe starting period. It allows you to enter the starting date of each CSPSR timeframe starting period. The first Report Timeframe Start Date is the same as the Assigned Date. The Start date is a read-only field. The Start Date of the CSPSR is always a non-editable field irrespective of whether the CSPSR is in Submitted/Non-submitted state or even if it is a copy of another CSPSR. **Start Date** of the new row always have the next date of the previous **End Date** pre-populated as read-only, and **End Date** can be added only one at a time. The **Start Date** of the CSPSR is auto-populated and reset to **Assigned Date** value only if the first timeframe row (first start as well as end date) is editable. The **Start Date** of the CSPSR is not updated based on the Assigned date, if this first timeframe row is non-editable. Whenever Start date is auto-updated and end date is already specified, the system displays the following warning message: Start Date for the reporting period has changed. Please update the End Date accordingly. When you enter the Start Date which is older than the latest End Date (previous row), the system displays the following error message: Start date must be same day, or after the latest end date. By clicking **OK**, the wrong Start Date is removed. Note: The CSPSR contains the number of events from Submitted to the Japanese Agencies and non-reportable events within the Reporting Period.
8	End Date	This field is a date entry field for the reporting timeframe ending period. It allows you to enter the ending date of each CSPSR timeframe starting period. This is an editable field. When you enter the End Date which is earlier than the same timeframe's Start Date, the system displays the following error message: End date must be after the Start Date By clicking **OK**, the wrong end date is removed. **Note:** The CSPSR contains the number of events from Submitted to the Japanese Agencies and non-reportable events within the Reporting Period. The System does not allow you to edit the previous reporting period and only allows to edit the current reporting period.

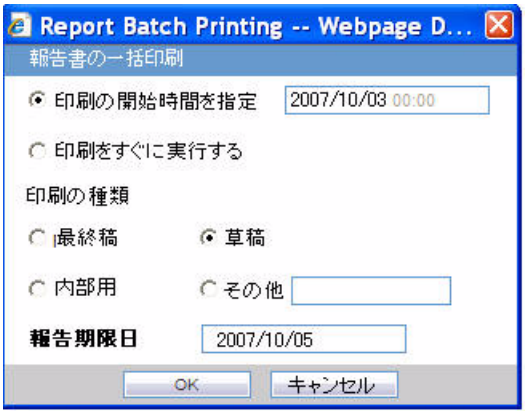
#	Field Name	Description
9	Add	You can add editable row by clicking this button. You can add only 1 reporting timeframe which can remain in Editable state in a CSPSR in single configuration. All the previous reporting timeframes are always in non-editable state. By default, in a freshly configured CSPSR (non-submitted, non-copied), there is no timeframe row to begin with until you add one row using the **Add** button. Whenever the first timeframe row is added, the **Start Date** is auto-populated based on the Assigned Date. When you generate a CSPSR, it is generated based on the last editable timeframe row. Once the report is marked with the **Submitted** status, all the timeframe rows are marked as **Non-editable**. If you do not have any editable timeframe row available in the CSPSR, only then **Add** button is enabled. Else, it is always disabled. The **Add** button adds editable fields for Start and End date. Each row has a number that starts from **1** and is incremented for each timeframe.
10	Delete	You can delete the editable row by clicking this button. The **Delete** button cannot delete the non-editable row. For removing previous non-editable rows, you can use the **RESET** button. This makes sure that you do not delete any timeframe rows which CSPSR has already submitted. When this is selected, the following warning message is displayed to confirm the operation: Would you like to delete the highlighted row?
11	Reset	When this button is clicked, all the existing timeframe rows (editable as well as non-editable) are deleted. Else, the past **Start** and **End** date records are non-editable. This **Reset** makes **Assigned Date**, **IBD**, and **JAD** editable as none of the non-editable timeframe rows exist now. When the **Reset** button is clicked, the following warning message is displayed: By using Reset, all the past data will be removed. Do you want to proceed? If you click **OK**, proceed with the reset. If you select **Cancel**, leave the past data in the schedule table. When you make copy of a configuration, the **Assigned Date**, **CSPSD**, and **CTPCSD** are non editable unless the **Reset** button is used.
12	#	

4.2.7.2.5 Security



#	Field Name	Description
1	Share this report with other users	
2	User Groups	
3	Add	
4	Remove All	
5	Remove	
6	Execute	
7	Modify & Execute	
8	OK	
9	Cancel	

4.2.7.2.6 Printing CSPSR



#	Field Name	Description
1	Report Batch Printing	
2	Run at	

#	Field Name	Description
3	Run Now	
4	Print As	
5	Final	
6	Draft	
7	Internal	
8	Other	
9	Due Date	
10	OK	
11	Cancel	

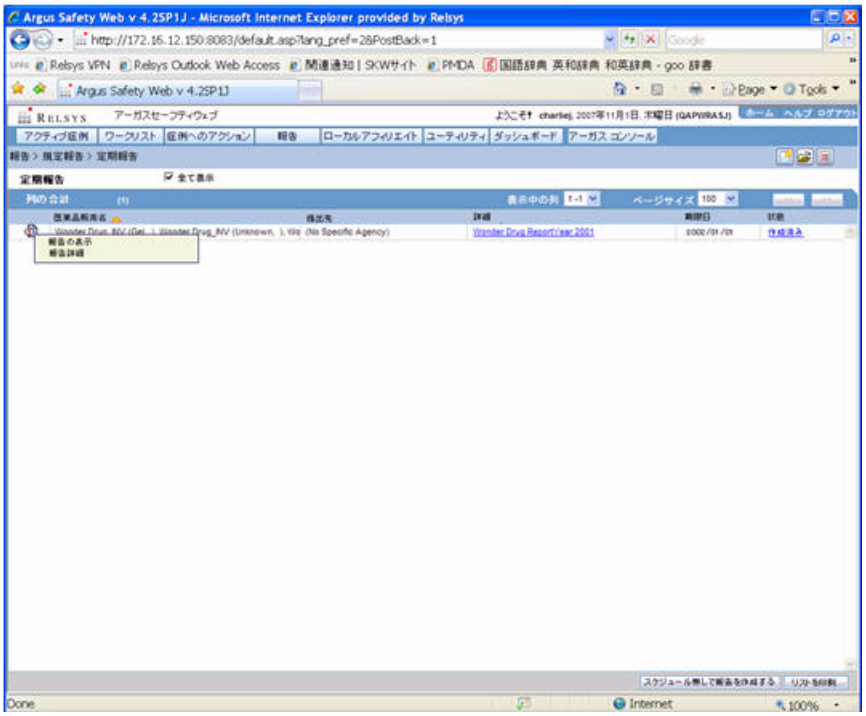
Generating the Document

The generation of the document is executed using the following process:

1. Click **View Report** in **Reports** > **Compliance** > **Periodic Reports**
2. Check-out the report from the **View and edit CSPSR** pop-up.
3. Edit the checked-out Word document
4. Check-in using the same **View and edit CSPSR** pop-up
5. Publish the PDF file (converting from the Checked-in Word document)

Printing Requirements

- The system allows you to print the report and update the report output in the Word document. The watermark is printed on the report when the **Draft**, **Internal** or **<Other>** is selected for printing.
- The change of the configuration for the same investigation timeframe can be done multiple times only before the status is changed to **Submitted**. The changes in the configuration after the **Submitted** status of the CSPSR is applied on the next investigational time period.
- From the **Reports** > **Compliance** > **Periodic Reports,** selecting **View Report** allows you to view the CSPSR Report in the Word document to upload the report.
  - When J user opens **Reports** > **Compliance** > **Periodic Reports** from the menu, Japanese UI is displayed for Periodic report list. The pop-up for the CSPSR view and edit is in Japanese.



#	Field Name	Description
1	PERIODIC REPORTS	
2	View All	
3	Total Number of Rows (1)	
4	Displaying Rows	
5	Page Size	
6	Trade Name	The Japanese UI displays available Japanese data in this field. When Japanese data is not available, the English data is displayed.
7	Destination	The Japanese UI displays available Japanese data. When Japanese data is not available, the English data is displayed. When Destination is not available, **No Specific Receiver** is displayed.
8	Description	The Japanese UI displays available Japanese data in this field. When Japanese data is not available, the English data is displayed.
9	Due Date	The English date format is **DD-MMM-YYYY**. The Japanese date format is **YYYY/MM/DD.**

#	Field Name	Description
10	Status	The Status appears in Japanese in Japanese UI, and in English in English UI and can have the following possible values: Scheduled Generated Approved Disapproved Submitted New Data Available No Longer Required
11	Create Unscheduled Report	
12	Print List	
13	View Report	
14	Report Details	

  - **Trade Name** section:

    The **Trade Name** section displays the multiple trade names using comma separated list of the selected products.

    The Trade Name displays the original product selected: either **English** or **Japanese**. If PSUR was created for the English product names, the English product name is used in the list. If the CSPSR is created with Japanese product names, the Japanese product name is used in the list.

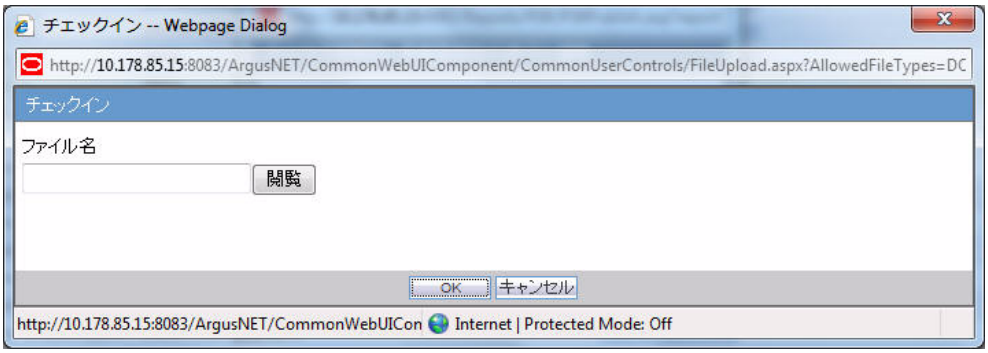
    If the selected product in the CSPSR does not have the Japanese Trade Name, the English Trade Name is displayed for that CSPSR.

- The report output is a Word Document. This works in the similar way to ePSUR publishing where you are allowed to edit the Word Output outside the system and once generated, can publish the FINAL Word Document.
  - When the report is generated and it has been never checked out, the center button displays **Check-out** to revise the document. At this time, the **Publish** button is disabled.
  - Check-out can be executed by one user only. Other users cannot check-in the checked-out files.
  - Once the check-out is executed, the **Check-out** button is changed to the **Check-in** button. This button is used to check- in the revised checkout file.
  - When the file is checked-in, the center button becomes the **Check-out** button.
  - When the file is not checked-out or not published, you can check-in/check-out the file as many times you want.
  - When the file is not checked-out or not published, the group which has access rights to this report can execute the **Check-in**, **Check-out**, and **Publish**.
  - The **View** button is always enabled (regardless of the **Check-in/Check-out** status). It displays the latest updated Word document or the PDF after final Publish.
  - The **Publish** button is enabled after the check-in has been performed atleast once. The **Publish** button is disabled when the document is checked-out.

- Once the final Word file is created, the Word document is saved in the repository. All the past CSPSR Word outputs are saved. When you update the Word document and upload it, the system overwrites the automatically generated document in the database.
- Once the **Publish** button is executed and the PDF file is created, the **Check-Out** button is disabled.
- Once the document has been checked-in, the **Check-in** button is changed to **Check-out**, and the **Publish** button is enabled to publish the PDF report from the Word document.
- The **Publish** button converts the checked-in word document to the PDF file.
- Once **Publish** is done, the Word document is no longer available. The **Check-in/Check-out** buttons are disabled only when the CSPSR is published and the label is changed to **Check-out**.

#	Field Name	Description
1	View and edit CSPSR	
2	Select necessary action	
3	Checkout	
4	Checkin	
5	View	
6	Publish	
7	Close	

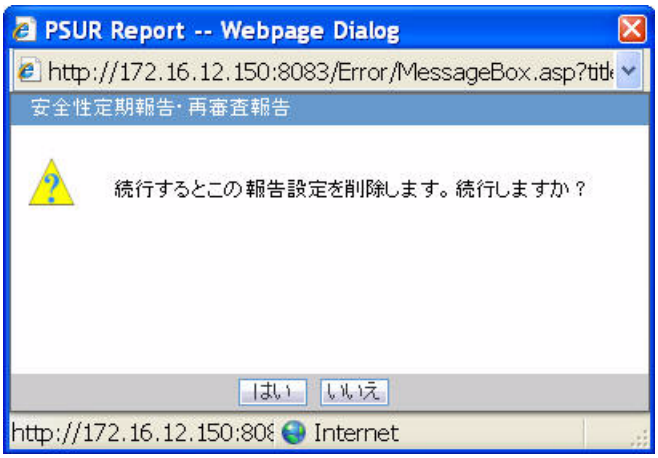
- When the **Check-in** button is clicked, the following pop-up is displayed to specify the file name. This can be done by either specifying the file name in the text box, or selecting the location using the **Browse** button.



#	Field Name	Description
1	Checkin	
2	File Name	
3	Browse	
4	OK	
5	Cancel	

- If the data is changed manually in the Word document, this change is not applied to the next report. You need to change the report again.
- The configuration of the CSPSR can be edited while the CSPSR is checked-out. The change is affected only when the CSPSR is created again.

4.2.7.2.7 Deleting A CSPSR



#	Field Name	Description
1	CSPSR	
2	Are you sure you want to remove this report configuration?	
3	Yes	
	No	

4.2.7.3 CSPSR - Cover

Summary: The CSPSR Cover is the cover page of the CSPSR Line Listing, and output includes the information of the configured product.

This form does not contain any particular case data.

#	Field Name	Description
1	Clinical Study Drug Serious Adverse Events etc. Case Periodic Safety Report	
2	Form	
3	Clinical Compound Number	This field represents the Clinical Compound Number of the selected product from Console Business Configuration/Product/License. Use ([1],[2],[3]…) numbering format for multiple Clinical Compound Numbers.
4	Ingredient Name	The generic name is entered in this field. If the license is withdrawn before the starting date of the CSPSR timeframe, the generic name is not displayed. If Japanese name is not available, this field can be left blank.

#	Field Name	Description
5	Amount and Formulation	This field represents the amount of the ingredients and formulation (from Dosage info) of the product. If multiple formulations are reported in the same form, enter the information for each formulation. The Strength and unit of the product, and formulation are listed in the following format: "Strength""unit" "Formulation" If the strength data is not available, only the formulation is listed. Use ([1],[2],[3]…) numbering for multiple information. If Japanese name is not available, the section is left blank.
6	Clinical Study Plan Submit Date	Enter the CSPSD from the CSPSR **Configuration/Scheduling** tab.
7	International Birth Date	This field represents the IBD from the Code List **Product**. Use ([1],[2],[3]…) numbering for multiple names.
8	Trade Name	The Trade Name is based on the selected product in the Configuration window. If there are multiple products (different amount, formulation, etc), use ([1],[2],[3]…) numbering with the trade names. You can use **Trade name (J Drug code)**. When the code is not available in the code lists, the code is not necessary. If there is a product that has multiple Japanese licenses, all of the trade names must be listed. This field is entered when the selected product is the marketed product (Clinical Trial for Partial Change), but if this is for the Study drug, this field is left blank.
9	Japan Award Date	Code List **Licenses -Japan Award date** Use ([1],[2],[3]…) numbering for multiple names. All the Japanese award dates are listed in this field. The Japanese Award date can be retrieved from **License** award date field for Japanese license Code List. If the license is withdrawn before the starting date of the CSPSR timeframe, the Japan Award Date is not displayed. This field is entered when the selected product is the marketed product (Clinical Trial for Partial Change), but if this is for the Study drug, this field is left blank.
10	Reporting Timeframe starting date (Assigned Date)	This field represents the Assigned Date from the **CSPSR Configuration Scheduling** tab.
11	Expected Indication	Enter Primary Indication from the Business Configuration/Product/Primary Indication. Use ([1],[2],[3]…) numbering for multiple Indications. If Japanese name is not available, this section is left blank.

#	Field Name	Description
12	Expected Use and Dosage	The information is not printed in this section. You need to enter the information in the Word document output.
13	Investigational Unit Timeframe	This field is used to enter the **Time frame Start Date** and **Time frame End Date** for this report. This denotes the Investigation timeframe for this report.
14	Number of the CSPSR report sent for this ingredient	This field denotes the total number of CSPSR report sent to PMDA including the current time. This starts from 1, 2, 3…
15	Study Phase	Enter **Console J** > **Business Configuration** > **Studies** > **study phase J** using this field. When there are multiple clinical studies that use the same Clinical Compound number, use ([1],[2],[3]…) numbering and list each study phase of all the studies using comma separated string against each number. It only considers the studies configured as **Selected Domestic Studies** in the **Product Selection** tab. If Japanese name is not available, this section is left blank.
16	Status of the Serious AE, etc. case occurrences	This field is used to enter **TBD** (As described in the Line Listing report)
17	Safety action based on the data analysis and safety countermeasure for the future	This field is left empty to enter the description in the output format.
18	Note	This field is left empty to enter the description in the output format.
19	From above reason, this reports Clinical Serious Case AE Periodic Reports	
20	YYYY?MM?DD? TBD	The Date report is created in the Japanese format. It is printed as the current database date converted into Japan time zone (using the Common Profile Switch under **Argus J** > **Reports** > **Offset** from GMT and is used to calculate Japanese date/time fields (in hours)) on which the report is being executed.
21	Address	This field represents the Address of the sender (A.3.1.4a-c). Format: TBD[A.3.1.4c][A.3.1.4b][A.3.1.4a] A line break is inserted if the address is reached to the maximum printable length for the line in the print. The address line can be 3 lines in one page, and if the 3rd line reaches the maximum length, it is printed to the next page. No spaces are used between the populated values. The **Address** and the **Name** are printed from center of the page (same as PMDA Expedited Reports Name and Address print)

#	Field Name	Description
22	Name	This field represents the Sender Identifier(Company Name (J), A.3.1.3b, A.3.1.3c, A.3.1.3d, A.3.1.3e) **Format:** TBD[Company Name (J)] [A.3.1.3b]space[A.3.1.3e]space[A.3.1.3d]space[A.3.1.3c] The print start point of [A.3.1.3b] is the same as [Company_Name_(J)] in above line. For the second line, empty space is printed between the populated values A line break is inserted, If A.3.1.2 reaches the maximum printable length for the line. There can be 2 lines in one page. And if the 2nd line reaches the maximum length, it is printed to the next page. . A line break is inserted, If combination of [A.3.1.3b] [A.3.1.3e] [A.3.1.3c] reaches the maximum printable length for the line. There can be 2 lines in one page. And if the 2nd line reaches the maximum length, it is printed to the next page. The **SENDERMIDDLENAME** is not printed if it does not exist The Address and Name is printed from center of the page (same as PMDA Expedited Reports Name and Address print)
23	Receiver identifier	PMDA Receiver identifier A.3.2.2d-f in _____ section. This is printed as follows: Receiver Identifier (A.3.2.2a, A.3.2.2c, A.3.2.2d, A.3.2.2f) **Format:** [A.3.2.2a][A.3.2.2c]space[A.3.2.2f]space[A.3.2.2d]space? - TBD

Additional Information

- This cover page has Japanese license information only.
- If all the information is the same through all the numbered items, enter the numbers with one information. When there is no data available, skip the data and only print the serial numbers for which the values are present.
- If the license is withdrawn before the Start Date of the CSPSR time frame, all the product information as well as the license information is not displayed.
- The overflow data is printed on the next page on the copy of this cover page that does not have any data other than the overflow data.
- For Ingredient Name, Indication, Study Development Phase, Amount, and Formulation, if source console values are not configured, fields on the paper form are left blank.

4.2.7.4 Clinical Study Periodic Safety Report - Line Listing

Summary: CSPSR Line Listing is the report of events that are serious (both Reported and Not Reported) during the specified investigational time period for Study drugs (including Study for partial change of the Marketed drugs).

- The past record is included in the report as cumulative Total Number of SOC and Terms.
- The number of the serious events which are either Reported or Not Reported to the PMDA within one investigational timeframe is the content for the report.
- Regardless of **Incomplete** or **Complete** report, all the events during the investigational timeframe are listed.
- If there are multiple events in one case, count each Reportable event separately. For example, if there are 2 same PTs available in the same case, the count is 1 SOC and 2 PTs.
- Domestic cases are listed in the **Domestic Study** column and foreign cases are listed in the other 2 columns.
- A case is included in the report for the current timeframe only if a significant Japanese follow-up is received for the case in the same timeframe. If there are no significant updates for the case, this case is not counted for the current period.
- If there are multiple follow-up updates (Significant or Non-significant) to a qualifying case in the same investigational time frame, count the events based on latest information on the events in the case and exclude the **Deleted** events during the timeframe. If the event is entered as **Serious**, but later in the same timeframe, this is changed as **Non Serious**, this event is not counted.
- The MedDRA version is the latest MedDRA J version at the time of report creation.
- The configured products that fall in **DRUGCHARACTERIZATION = 1 (SUSPECTED)** or **3 (INTERACTION)** are collected. **2 (Concomitant)** is not included.
- The date cut off for the data inclusion is based on the case's Japan first information Aware Date (in **PMDA** > **General** tab of the Case Form). If this is a follow-up case, the Aware (latest significant follow-up) Date.
- The **Serious** events must be **Related** events to be included in the list.
- An event which is included in the past **CSPSR** report is included in the **Cumulative Total** section of the count in the report.
- For identifying the Japanese license, the license authorization country in the license configuration in Console is used. For the count of the foreign data, all configured products that have the same ingredients (regardless of the existence of Japanese license in this family) is considered as the target.
- The count for the event starts from 4/1/2009 even if the Start Date is calculated to before 4/1/2009.
- When the End Date is set as past date, any updates/new data that meet above condition in between the End Date and the current date are not included in this line listings. The data is the latest in the given timeframe, and not between the investigational timeframe Start Date and the Report Generation Date. This is achieved when you have enabled DLP and has configured the **Use DLP Case Version** radio option for CSPSR configuration.

- If there is 0 count on any counting numbering sections of the Line Listing, **-** is printed.
- From 2nd and subsequent pages, the table header rows are repeated at the top of the each page.

Basic Data Retrieval Rule:

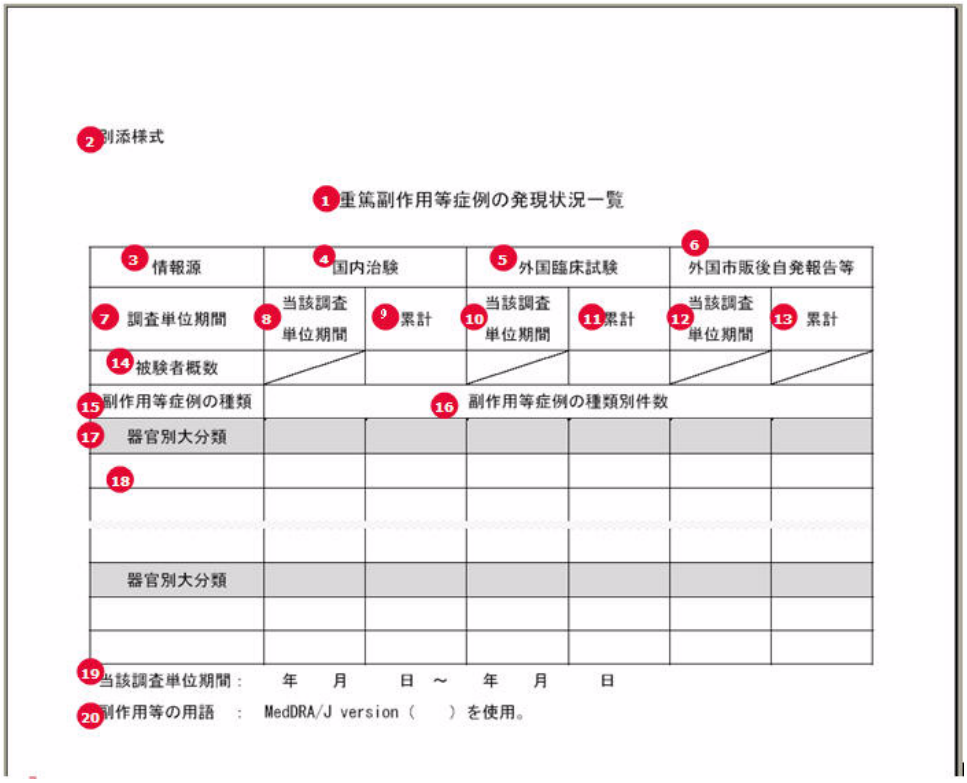
Cumulative Total:

- If the CSPSR starting date is before 04/01/2009, the cumulative is the count of Serious AEs that are collected between 04/01/2009 to the end of the current investigation timeframe.
- If the CSPSR starting date is after 04/01/2009, the cumulative is the count of Serious AEs that are collected between the Start Date to the end of the current investigation timeframe.

Investigation Time Frame

The Serious AEs from the cases collected in this investigation timeframe from among the cases retrieved by Cumulative Total.

4.2.7.4.1 TBD (No Heading in PMDA Reports Document)



#	Field Name	Description
1	Serious AE, etc. Case Occurrence Status Line Listing	This field represents the title of the paper form.
2	Attached paper form	This field represents the header of the paper form.
3	Information Source	This field represents the title of the row.

#	Field Name	Description
4	Domestic Clinical Study	This field represents the title of the column. This column has data only from the report source: Clinical study and Incident Country = Japan. It only considers the cases which contain the studies configured as **Selected Domestic Studies** in the **Product Selection** tab.
5	Foreign Clinical Study	This field represents the title of the column. This column has data only from the report source: Clinical Study and Incident Country <> Japan. It only considers the cases which contain the studies configured as **Selected Foreign Studies** in the **Product Selection** tab.
6	Foreign Marketed Spontaneous Report	This field represents the title of the column. This column has data only from the report source: Not Clinical Study and Incident <> Japan.
7	Investigation Time Frame	This field represents the title of the row. Static text.
8	This investigation period	This field represents the title of the column. This column collects count information in this investigation period only.
9	Cumulative Total	This field represents the title of the column. This column collects total number of count information in the entire reporting period starting from the first **Assigned Date** to the end of current investigation period. If the configuration is set (checked for **Exclude the event count from the cumulative total if the event doesn't meet the condition**), events that were reported in the past but as the condition has been modified in the current timeframe they no longer meet the condition, are removed.
10	This investigation period	This field represents the title of the column. This column collects count information in this investigation period only.
11	Cumulative Total	This field represents the title of the column. This column collects the total number of count information in the entire reporting period starting from the first **Assigned Date** to the end of current investigation period.
12	This investigation period	This field represents the title of the column. This column collects count information in this investigation period only.
13	Cumulative Total	This field represents the title of the column. This column collects the total number of count information in the entire reporting period starting from the first **Assigned Date** to the end of current investigation period.
14	Number of subjects	This information is captured from the **CSPSR** tab.
15	AE, etc Case classification	This field represents the title of the column
16	AE, etc. Case Count	This field represents the title of the column
17	SOC name in Japanese	The SOC count is the count of cases (not AEs). The number is collected for this inv. Period and the total of entire CSPSR time.

#	Field Name	Description
18	PT names	All the serious AEs are counted and entered for this inv. Period and entire CSPSR time.
19	This investigation time frame: YYYY?MM?DD????YYYY?MM?DD? - TBD	This investigation timeframe is entered using the Japanese date format.
20	Terms for AE: MedDRA/J version ( ) was used.	The used MedDRA/J version must be entered in the brackets.

4.2.8 Seiyakukyo Line Listing Report (Individual Report Common Line List)

Seiyakukyo Line Listing report is a periodic report format specified by the JPMA. This report is to be used by pharmaceutical companies in Japan to send case reports to medical institutions. It is mandated by PMDA to report study cases to medical institutions and is required to be fully compliant in Japan.

Seiyakukyo periodic report is handled in the similar manner as the other Japanese periodic reports - PSR/ReSD, and CSPSR. At a high level, it has a similar Configuration screen, similar Generation, Publishing, and Handling process as other Japanese Periodic reports. However, the report output format and data is different so as to match the Seiyakukyo format.

4.2.8.1 Configuration Screen

- A new menu item - **Individual Report Common Line List** is added in **Console** > **Groups** > **Menus** section for the Argus Groups for Seiyakukyo report.
  - It is added under **Reports** > **Periodic Reports** right after **Clinical Study PSR** menu option.
  - It is marked enabled by default for **Administrator Group**.
  - It is marked enabled by default during New Argus group creation.
  - It is only displayed if **Console** > **System Management** > **Enabled Modules** > **Japanese** module is enabled.
- A new menu item - **Individual Report Common Line List** is added under **Argus Safety** > **Reports** > **Periodic Reports** menu.
  - It is added under **Reports** > **Periodic Reports** right after the CSPSR menu option.
  - This menu item is only available in Argus Safety if following conditions are met:

    Console > **Access Management** > **Users** > **User Type** of the current user is configured as **ARGUS J USER**.

    Console > **System Management** > **Enabled Modules** > **Japanese module** is enabled.

    Console > **Access Management** > **Groups** > **Menus** section for Argus Groups has **Reports** > **Individual Report Common Line List** marked **Enabled** for at least one user groups for the current user.
- Clicking on this menu in Argus Safety displays the existing **Periodic Reports Library** screen, which lists all the configured Seiyakukyo reports available in the system.

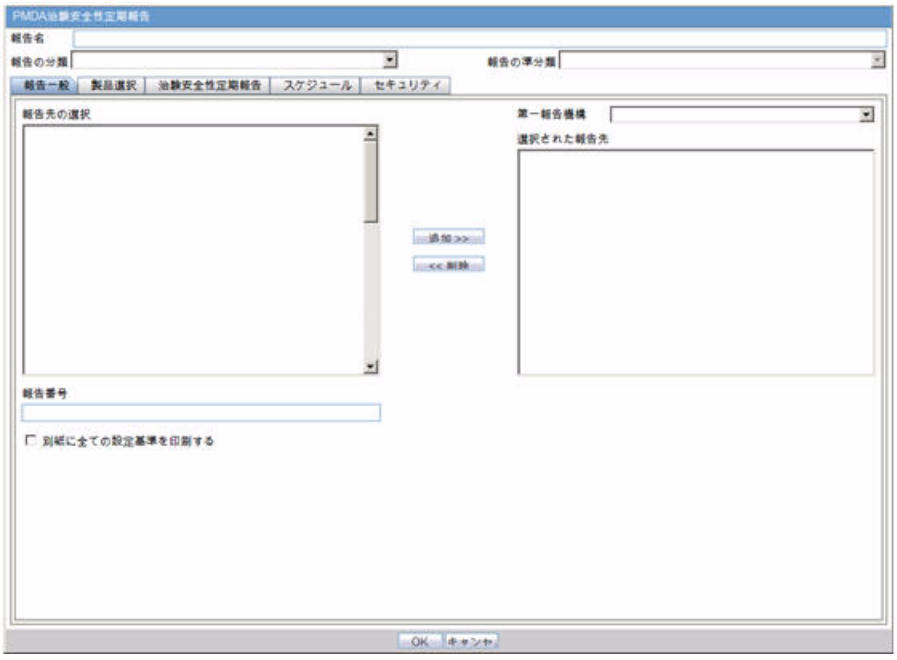
  - The functionality of this screen remains the same as existing except for the following:

    The page breadcrumb for the **Periodic Reports Library** screen for Seiyakukyo is displayed as:
    Reports > **Periodic Reports** > **Serious, Unlisted AE Individual Case Communication Line List**

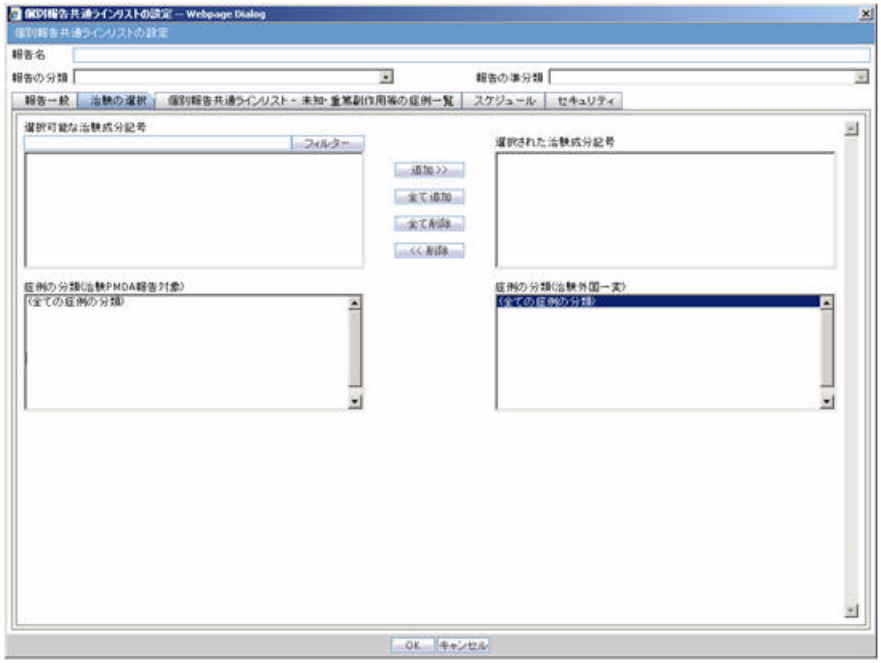
    The screen name for this screen is displayed as **Serious, Unlisted AE Individual Case Communication Line List**.

    When you click the **Open** button for a submitted Seiyakukyo report whose configurable becomes non-editable, the following warning message is displayed:
    This configuration is not modifiable because the status of this Individual Case Communication Line List is Submitted

- Clicking **New** or **Open** buttons on **Periodic Report Library** screen for Seiyakukyo reports displays the Configuration screen for Seiyakukyo reports which has 5 tabs similar to the CSPSR Configuration screen with following names. The Page Title text is: **Individual Report Common Line List**.
  - Subject of Report
  - Individual Report Common Line List
  - Scheduling
  - Security
- The Subject of the **Report** tab is the same as the existing Subject of the **Report** tab for CSPSR.



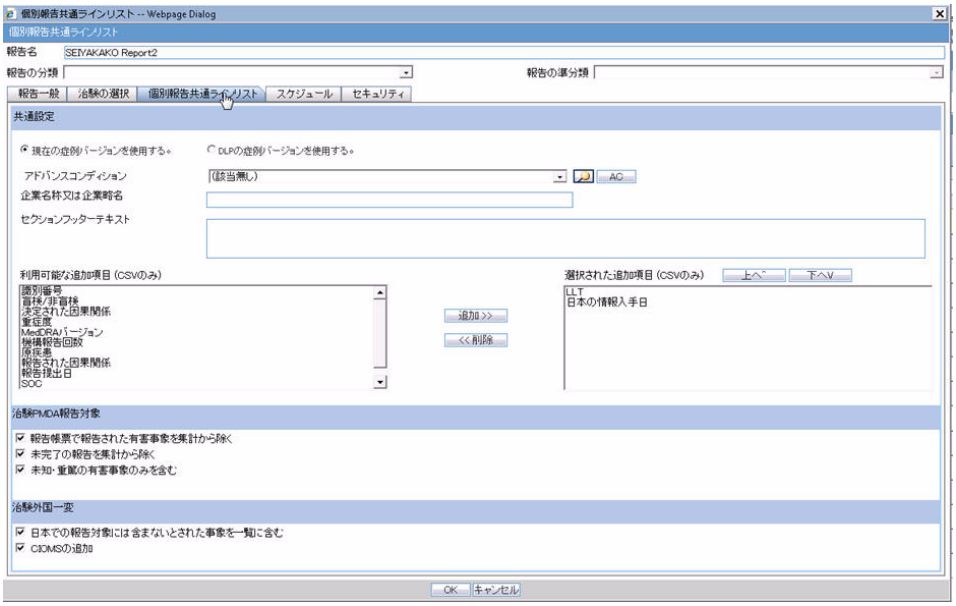
- The **Study Selection** tab has the following functionality:



#	Field Name	Description
1	Study Selection	
2	Filter	This button is available adjacent to the **Available Clinical Compound Numbers** textbox to allow filtering the data in the **Available Clinical Compound Numbers** multi-select list box. When you click this button, the data is refreshed in the **Available Clinical Compound Numbers** multi-select list box based on the search text specified by you in the textbox. Like search is performed based on the text specified by you. For example, If you have specified **ABC** as the search text, it performs case-insensitive text for **%ABC**%. The maximum allowed length of the **Filter** textbox is 70 characters.
3	Available Clinical Compound Numbers	It lists distinct Clinical Compound Numbers for all the licenses which are configured in the Console application.
4	Selected Clinical Compound Numbers	This listbox is populated based on your selection and removal of Clinical Compound Numbers by using **Add** and **Remove** buttons from/to the **Available Clinical Compounds** listbox. This is a mandatory field. If it is not specified, and the **OK** button is clicked, the following error message is displayed: Clinical Compound Number is not selected
5	Add	This field allows you to move the selected item(s) from left hand listbox to the right hand listbox.
6	Add All	This field allows you to move all the items from the left hand listbox to the right hand listbox.

#	Field Name	Description
7	Remove All	This field allows you to move all the items from the right hand listbox to the left hand listbox.
8	Remove	This field allows you to move the selected item(s) from the right hand listbox to the left hand listbox.
9	Classifications for Clinical and Domestic Study Cases	It lists all the Case Classification (J) values from the Console code list. If J is not available, the corresponding English value is displayed. You can select multiple values in this listbox by using **Ctrl + Click** and **Shift + Click** combinations. The first option in this list is always displayed as: All Case Classifications These case classifications are used for fetching the case data for Clinical and Domestic study cases reporting in Seiyakukyo report.
10	Classifications for Foreign "Ichihen" Study Cases	It lists all the Case Classification (J) value from the Console code list. If J is not available, the corresponding English value is displayed. You can select multiple values in this listbox by using **Ctrl + Click** and **Shift + Click** combinations. The first option in this list is always displayed as: All Case Classifications These case classifications are used for fetching the case data for Foreign **Ichihen** study cases reporting in Seiyakukyo report.

- Seiyakukyo Report tab has the following functionality:



#	Field Name	Description
1	Individual Report Common Line List	N/A
2	Common Configuration	N/A

#	Field Name	Description
3	Company Name or Company abbreviation	You can specify the value of the Company Name to be printed in the second column of Seiyakukyo report using this field. The maximum allowed length of this textbox is 60 characters. It allows English as well as Japanese characters.
4	Section Footer Text	You can specify a text to be printed as footer text at the end of each section in the report output using this field. The maximum allowed length for this textbox is 200 characters. It allows English as well as Japanese characters.
5	Available Additional Columns (CSV Only)	This field lists all the available additional fields that can be added to the Seiyakukyo report CSV output. These are not applicable to the Word output. The following fields are available in this list in the alphabetical order: ACK Number Blinded / Not Blinded Determined Causality Event Intensity Japan Information Receipt Date LLT MedDRA Version Number of times this report is submitted to PMDA Primary Disease Reported Causality Report Submission Date SOC Study Name
6	Selected Additional Columns (CSV Only)	It lists all the selected additional fields that are added to the Seiyakukyo report CSV output. These are not applicable to the Word output. You can move items between Available and Selected Additional Columns using the **Add** and **Remove** buttons. While adding items, these items are listed in the same order in which they are added. You can move items up and down using **Up** and **Down** buttons. The Seiyakukyo report output includes these columns at the end in the same order as specified in this list.
7	Add	This field allows you to move the selected item(s) from the left hand listbox to the right hand listbox.
8	Remove	This field allows you to move the selected item(s) from the right hand listbox to the left hand listbox.

#	Field Name	Description
9	Up ^	This field allows you to move the selected item in the **Selected Additional Columns**, one position closer to top of the list.
10	Down V	This field allows you to move the selected item in the **Selected Additional Columns,** one position closer to the bottom of the list.
11	Clinical and Domestic Study Cases	N/A
12	Exclude events which were reported by paper report forms	If this checkbox is checked, all the events which are reported through paper reports are excluded. This logic is applicable only for Clinical and Domestic Study cases for which events are reported based on Expedited/E2B reports. It is unchecked by default.
13	Exclude Incompletion reports	If this checkbox is checked, all the events which are reported through Expedited/E2B reports where the value of J.6 (Mhlwadmicsrcompleteclass) = 1 (Incomplete) are excluded. This logic is applicable only for Clinical and Domestic Study cases for which events are reported based on Expedited/E2B reports. It is unchecked by default.
14	Include only serious unlisted events	You can specify the criteria for printing the events under Regular and Domestic Study cases category using this field. It is unchecked by default.
15	Foreign "Ichihen" Study Cases	N/A
16	Include foreign AE marked as "Not include for the report in Japan"	If this checkbox is checked, all the events in the cases which are marked as **Not to be reported to Japan** in the **Case Form Events** tab are also included. This logic is applicable only for Foreign **Ichihen** study cases for which events are reported based on case data directly. It is unchecked by default.

#	Field Name	Description
17	Append CIOMS reports	If this checkbox is checked, the CIOMS reports are created and added at the end of Seiyakukyo report output for all the cases which are printed under Foreign **Ichihen** Study Cases section. These CIOMS report are printed for the earliest **Valid Japanese license** for the first suspected product in the case. If the first suspected product does not have a **Valid Japanese license**, the next suspected product which satisfies this criterion is picked-up in the same order in which they are present in the case. Once the Seiyakukyo is generated as FINAL, these reports are listed in the Case under the **Regulatory Reports** tab in the similar manner as for English PSUR. These reports are added only in the PDF format (not in CSV), when the Seiyakukyo report is published. These reports are generated at the time of Seiyakukyo generation. The **Generation Status** dialog box displays the label **Generating CIOMS reports** for this task during the Seiyakukyo generation process. Although, generated at this stage, these CIOMS reports are visible to users after the Word format is published into PDF format. Even if you modify the Events/Cases printed in the application generated Word/CSV formats of Seiyakukyo report, the application still prints the CIOMS reports based on the application generated case list under Foreign **Ichihen** Study Cases section. It is unchecked by default.
18	DLP support	It displays 2 options to allow support of DLP for fetching case data for Foreign **Ichihen** study case: **Use Current Case Version** and **Use DLP Case Version**. This radio button control is only displayed if DLP is enabled. Based on the PSR/CSPSR configuration for DLP, the report is executed accordingly using the latest Case Revision or using the DLP Case Revision. **Use Current Case Version** is always checked by default.

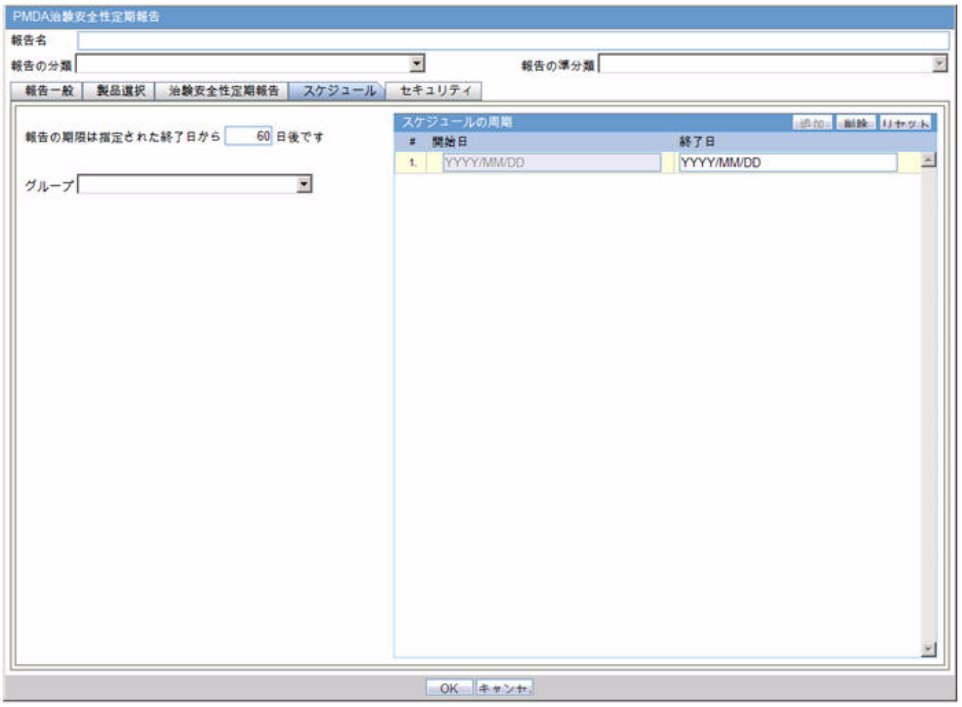
- The **Scheduling** tab is the same as the existing **Scheduling** tab for CSPSR, except for the following:
  - The following date fields are not displayed as they are not applicable to the Seiyakukyo reports. All the validation checks related to these fields are also not applicable to the Seiyakukyo reports:

    Assigned Date

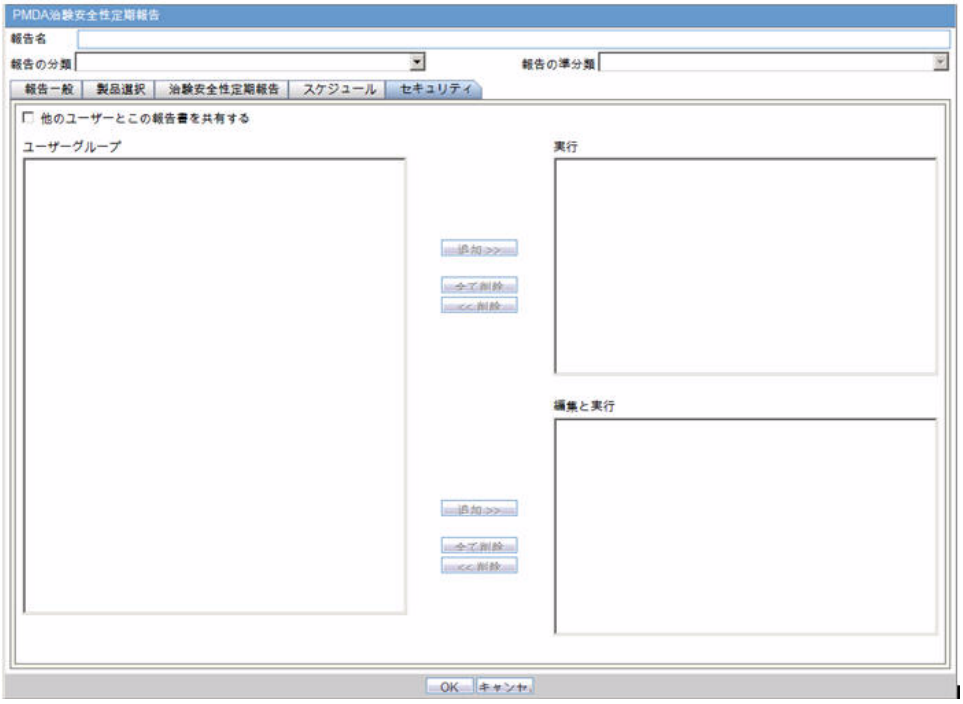
    Clinical Study Plan Submit Date

    Clinical Trial for Partial Change Plan Submit Date
  - The Start Date of first timeframe is editable as long as this timeframe is not submitted. However, the Start Date of second timeframes and onwards keep

following the existing logic of being disabled and pre-populated as next day of the previous timeframe End Date.



- The **Security** tab is the same as the existing **Scheduling** tab for CSPSR:



4.2.8.2 Report Output Format

- This report prints information from two types of study cases:

  - Clinical and Domestic Study Cases
  - Foreign **Ichihen** Study Cases
- The report output prints the events from these 2 types as 2 separate sections starting from new pages.
- Within each of these 2 types, the report output prints the events for each of the configured Clinical Compound Numbers starting from new pages as well.

4.2.8.3 Report Output Filter Criterion

- **Regular (Clinical) and Domestic Study Cases** - All the data is fetched based on the events reported in the Expedited/E2B reports already reported to PMDA.
  - Only the Expedited/E2B reports sent to the reporting destinations which are configured as the **Seiyakukyo Configuration** > **Subject of Report** tab > **Primary Agency** are considered.
  - Only the Expedited/E2B reports whose cases have at least one of their Case Classifications configured as **Seiyakukyo Configuration** > **Study Selection** tab > **Selected Classifications for Regular and Domestic Study Cases** are considered.
  - Only the Expedited/E2B reports that have **J.11 (mhlwcompoundnum)** element value same as one of the values configured as **Seiyakukyo Configuration** > **Study Selection** tab > **Selected Clinical Compound Numbers** are considered.
  - Only the Expedited/E2B reports that have **J.4a (mhlwadmicsrcasenumclass)** element value as 8, 9, 10, 11, 12, 13, and 14 (reporting categories - H, I, J, K, L, M and N) are considered.
  - All Nullification and Downgrade reports are ignored. However, their Initial and Follow-up reports that fall within the Seiyakukyo current timeframe are still considered.
  - If multiple Initial or Follow-up Expedited/E2B reports for any product license (any series of Expedited/E2B reports) fall within the current timeframe, all of them are considered.
  - Only the Expedited/E2B reports that have Report Submission Date (GMT) between and including the Start and End date (after conversion to GMT based on database time zone offset) configured for the current timeframe of the Seiyakukyo report are considered.
  - If the checkbox to include only Serious and Unlisted events is configured, it includes only those reported events from the Expedited/E2B reports that are also Serious and Unlisted in the case. Else, all the reported events from the Expedited/E2B reports are considered.

    Unlisted - Specified as Unlisted in the case against atleast one Japanese license (License Drug Authorization Country as Japan). The Listedness specified as **Unknown** is not considered.

    Serious - The Event is specified as Serious.
  - If the checkbox to exclude incompletion reports is checked on the **Individual Report Common Line List** configuration tab, any Expedited/E2B report that have **J.6 (Mhlwadmicsrcompleteclass)** element value as **1** (Incomplete) is ignored.

  - If the checkbox to exclude Paper reports is checked on **Individual Report Common Line List** Configuration tab, all PMDA Paper Expedited reports are ignored.
  - If the same AE/Infection event is reported in multiple eligible reports from the same case, all of them are reported multiple times in the Seiyakukyo report as well.
  - All the events in Seiyakukyo report are sorted in the following order:

    Report Submission Date (Old to New)

    Case ID Number (ascending)

    Events as ordered in the expedited/E2B report

- **Foreign Ichihen Study Cases** - All the data is fetched based on the events present in the case data.
  - Only the cases that have Country of Incidence other than Japan are considered.
  - Only the cases that have at least one of their Case Classifications configured as **Seiyakukyo Configuration** > **Study Selection** tab > **Selected Classifications for Foreign Ichihen Study Cases** are considered.
  - Only the cases that have atleast one of their Japan Information Receipt Date (significant follow-up or initial receipt date) between and including the Start and End date configured for the current timeframe of the Seiyakukyo report are considered.
  - Only the cases that have one of their Japanese licenses as present in the **Case Form** > **Event Assessment** tab and have the same Clinical Compound Number configured as **Seiyakukyo configuration** > **Study Selection** tab > **Selected Clinical Compound Numbers** are considered.
  - Only those events from the cases that have the Seiyakukyo products specified as:

    Related - At least one of the **As Reported** and **As Determined Causality** in the case is specified as Reportable for this Product Event combination.

    Unlisted - Specified as Unlisted in the case against at least one Japanese license (License Drug Authorization Country as Japan). The Listedness specified as **Unknown** is not considered.

    Serious - The event is specified as **Serious**.

- If the checkbox to include foreign AE marked as **Not include for the report in Japan** is checked on the **Individual Report Common Line List** Configuration tab, those events are also included. Else, such events are ignored from the cases.
- All the events in the Seiyakukyo report are sorted in the following order:
  - Japan Information Receipt Date (significant follow-up or Initial Receipt Date) (Old to New)
  - Case ID Number (ascending)
  - Events as ordered in the case

4.2.8.4 Report Output Field Mappings

#	Field Name	Description
1	Serious, Unlisted AE Individual Case Communication Line List	This represents the title of the paper form. It is a fixed text to be printed in the top center of the Report Output table.
2	Clinical Compound Number	Clinical Compound Number of the report/case. For Clinical and Domestic studies, it prints **J.11 (mhlwcompoundnum)** element value from the expedited/E2B report. For Foreign **Ichihen** studies, it prints the Clinical Compound Number from the License Configuration for the Japanese licenses present in **Case Form** > **Event Assessment** tab.
3	Company name or Company name abbreviation	If you have specified the Company Name to be printed in the **Individual Report Common Line List** configuration tab, that text is printed as it is for all the event rows. Else, it is left blank.
4	Management No. (Case No)	The Argus Case ID number for the corresponding event is printed in this field.
5	Adverse Event (MedDRA-PT)	This field represents the name of the Serious and Unlisted MedDRA J Term (B.2.1.2.b) **For clinical and domestic studies:** It prints **MedDRA PT (J)** term based on the **B.2.1.2.b (REACTIONMEDDRAPT)** value from the Expedited/E2B report. For Expedited/E2B reports with **J.4a (mhlwadmicsrcasenumclass)** element value as 12,13, and 14 (reporting categories L, M and N), it prints fixed text -**Research Report** for L and M, and **Measures Report** for N. Other Patient, Event, and Product Dosage fields in Seiyakukyo report for these reporting categories are left blank as this information is not present in the Expedited/E2B reports for these reporting categories. For decoding the MedDRA PT code from the Expedited/E2B report into the J Term, latest MedDRA dictionary configured for event encoding is used. For foreign **ichihen** studies: It prints MedDRA PT (J) term from Case Event record.

#	Field Name	Description
6	Outcome	This field represents the Reaction Outcome (B.2.i.8) **For clinical and domestic studies:** It prints the following Japanese description text for the E2B code values from the **B.2.i.8 (REACTIONOUTCOME)** value from the Expedited/E2B report. For reporting categories L, M, and N, it is left blank. For foreign **ichihen** studies: It prints the Event Outcome (J) value from the Case Event record.
7	Gender	This field represents the Patient Gender (B.1.5). For clinical and domestic studies: It prints the E2B M2 Japanese description based on the **B.1.5 (PATIENTSEX)** value from the Expedited/E2B report or the case. If B.1.5 is not available, print **Unknown** For reporting categories L, M, and N, it is left blank. For foreign **ichihen** studies: It prints the Patient Gender (J) value from the Case Patient record. If no value is available in the case, print **Unknown**
8	Age	This field represents the Patient Age (B.1.2.2/B.1.2.2.1/B.1.2.3) It prints the Patient Age value based on the E2B logic for Patient Age elements. For example, If the **Child Only** checkbox in Case is checked, only **GESTATIONPERIOD (B.1.2.2.1)** is transmitted. If it is not checked, and if **PATIENTONSETAGE (B.1.2.2)** is specified, only it is transmitted else **PATIENTAGEGROUP (B.1.2.3)** is transmitted. For **PATIENTONSETAGE**, **age (B.1.2.2a)** value is printed followed by the E2B M2 Japanese description of the Age Unit (B.1.2.2b) without any space in between . For **PATIENTAGEGROUP**, E2B M2 Japanese description of **B.1.2.3** is printed. For **GESTATIONPERIOD**, **TBD** is printed as fixed text followed by the Gestation period (**B.1.2.2.1a**) value and the E2B M2 Japanese description of the unit (**B.1.2.2.1b**) without any space in between. For **PATIENTONSETAGE**, if the unit value is Decade (B.1.2.2b = 800), special printing rule is followed. For reporting categories L, M, and N, it is left blank.

#	Field Name	Description
9	Dose	This field represents the Product Dose Information (B.4.k.5.1~B.4.k.5.5/B.4.k.6) In case of multiple dosages for the Seiyakukyo product(s), all the dosages are printed in the same cell, in the same order as in the Expedited/E2B report or as per the Product and Dosages order in the case. Each new dose information is printed after leaving a blank line and in alignment with the corresponding dose Start/Stop date value which is printed in the next column. For Clinical and Domestic studies, each dose information is printed using the following format: [B.4.k.5.1][B.4.k.5.2 (using E2B M2 Japanese description)] [B.4.k.5.3]?/[B.4.k.5.4][B.4.k.5.5(using E2B M2 Japanese description)] - TBD ([B.4.k.6(If this does not exist, then its braces for this value are not printed. However, a blank line is left to align the Dosage Information with the corresponding dosage dates values in the adjacent column.)]) For reporting categories L, M and N, it is left blank. For foreign **ichihen** studies, each Dose Information is printed in the following format using the value directly from the Case Product Dosage Record: [Dose][Dose Unit (J)] Code List/Dosage Frequency/[Number]TBD/[Unit Number][Unit (J)] ([Dose Description (J)]) - If this does not exist, then its braces for this value is not printed. However, a blank line is left to align the Dosage Information with the corresponding dosage dates values in the adjacent column.

#	Field Name	Description
10	Dose Start Date ~ Dose Stop Date (Dose interval)	This field represents the Product Dosage Start/Stop Dates B.4.k.12 B.4.k.14 (B.4.k.15) In case of multiple dosages for the product(s), all the dosage dates are printed in the same cell, in the same order as in the Expedited/E2B report or in the case. Each new Dosage Date is printed after leaving a blank like and in alignment with the corresponding dosage information value which is printed in the previous column. For reporting categories L, M, and N, it is left blank. For foreign **ichihen** studies, each dosage date is printed using the Dose Start Date, Dose End Date, and Dose Duration values from the Case Product Dosage record in the same format as specified for Clinical and Domestic studies. Dose duration value is converted from seconds into appropriate unit using the same logic as used in E2B for B.4.k.15.
11	AE, etc. onset date	This field represents the Reaction Onset Date (B.2.i.4) For Clinical and Domestic studies, it prints the **REACTIONSTARTDATE (B.2.i.4a and B.2.i.4b)** value. For reporting categories L, M, and N, it is left blank. For foreign **ichihen** studies, it prints the Event Onset Date from Case Event Record.
12	Country	This field represents the Country of Incidence (A.1.2) For Clinical and Domestic studies, it prints the E2B M2 Japanese description based on the **A.1.2 (OCCURCOUNTRY)** value from the Expedited/E2B report. For foreign **ichihen** studies, it prints the Country Name (J) value from the Case Record.
13	Information Source	This field represents the Report Type (A.1.4) For clinical and domestic studies, it prints the E2B M2 Japanese description based on the **A.1.4 (REPORTTYPE)** value from the Expedited/E2B report. For foreign **ichihen** studies, it prints the Report Type (J) value from the Case Record.
14	Report Type 7 days/15 days	This field represents the meeting Expedited Report Criteria (A.1.9) For clinical and domestic studies, it prints **7 days** or **15 days**, if the value of **A.1.9 (FULFILLEXPEDITECRITERIA)** is 1 or 2 respectively, in the Expedited/E2B report. For Foreign **Ichihen** studies, it is left blank.

#	Field Name	Description
15	Subject timeframe	This field represents the Reporting Timeframe considered for the AE. It prints the Seiyakukyo report current timeframe. The same values are printed in all the rows.
16	For the AE terms, MedDRA/ J version ( ) is used.	This field represents the MedDRA J version used for this report. It prints the MedDRA version as currently configured in the application for event encoding. This is repeated at the end of each **Clinical Compound Number** section.
17	Any additional columns added by the user in configuration (applicable only to CSV output)	**Study Name:** For clinical and domestic studies, it prints the value of **A.2.3.2 (SPONSORSTUDYNUMB)** from the Expedited/E2B reports. For foreign **ichihen** studies, it prints **Study ID (J)** from the case record. If **Study Name (J)** is not available in the case, print the corresponding English value. **Blinded / Not Blinded:** For all types of cases, it prints the Japanese text - **Blinded** or **Not Blinded,** based on the **Case Form** > **Study Information** > **Study Type** field value for the corresponding case. **SOC:** For clinical and domestic studies, it prints the MedDRA SOC (J) Term based on the **B.2.1.2.b (REACTIONMEDDRAPT)** value from the Expedited/E2B report. For decoding the MedDRA PT code from the Expedited/E2B report into J Term, latest MedDRA dictionary configured for Event Encoding is used. For foreign **ichihen** studies, it prints the **MedDRA SOC (J)** Term from the Case Event record. LLT: For clinical and domestic studies, it prints the **MedDRA LLT (J)** Term based on the **B.2.1.2.b (REACTIONMEDDRALLT)** value from the Expedited/E2B report. For decoding the MedDRA PT code from the Expedited/E2B report into J Term, latest MedDRA dictionary configured for event encoding is used. For foreign **ichihen** studies, it prints the MedDRA LLT (J) Term from the Case Event record. **MedDRA Version**: For clinical and domestic studies, it prints the MedDRA version as used in **B.2.i.2.a (REACTIONMEDDRAVERSIONPT)** from the Expedited/E2B report. For foreign **ichihen** studies, it prints the MedDRA version from the case for that Event Encoding.

#	Field Name	Description
		Report Submission Date: For Clinical and Domestic studies, it prints the corresponding Expedited/E2B Report Submission date after converting it into Japanese timezone based on the **Argus J** > **Reporting** > **Offset from GMT** Common Profile Switch that is used to calculate Japanese date/time fields for Interchange-J (in hours). For Foreign **Ichihen** studies, it is left blank. **Japan Information Receipt Date:** For Clinical and Domestic studies, it prints **J.3b (mhlwadmicsrinfoobtndatesource)**. For Foreign **Ichihen** studies, it prints the Japan Aware date. ACK Number: For Clinical and Domestic studies, it prints the eight digit **PMDA ACK number** received for the corresponding Expedited/E2B report. For Foreign **Ichihen** studies, it is left blank. Number of times this report is submitted to MHLW: For clinical and domestic studies, it prints **J.5 (mhlwadmicsrmhlwcumreporttimes)** element value. For Foreign **Ichihen** studies, it is left blank. **Primary Disease:** For all types of cases, it prints the **Condition (J)** value as present in **Case Form** > **Patient** tab > **Other Relevant History** section. Only those items are printed which have **Primary Disease** text present in the **Notes (J)** field. In case multiple items have to be printed, then these are printed in separate lines in the same cell. Event Intensity: For all types of cases, it prints the **Case Form** > **Event** tab > **Intensity (J)** field value.

#	Field Name	Description
		Reported Causality: Only one value is printed for this field based on the Reported Causality values specified for those products in the case, whose valid Japanese licenses have the same Clinical Compound Number for which this event is being printed. Only the causality values that are related to the current event being printed are considered. The following rule is used to determine the value that is printed in the report output. **Related** - If any of the Reported Causalities is Reportable (**Consider Expeditable to Authorities** is checked in Console Code list) **Not related** - Else, if any of the Reported Causalities excluding Unknown is not reportable **Unknown** - Else, if any of the Reported Causality is Unknown **No value** - Else, if all the Reported Causalities are blank. **Determined Causality:** Only one value is printed this for field based on the Determined Causality values specified for those products in the case, whose valid Japanese licenses have the same Clinical Compound Number for which this event is being printed. Only the causality values that are related the current event being printed are considered. The following rule is used to determine the value that is printed in the report output. **Related** - If any of the determined causalities is Reportable (**Consider Expeditable to Authorities** is checked in Console Code list) **Not Related** - If any of the determined causalities is Reportable (**Consider Expeditable to Authorities** is checked in Console Code list) **Unknown** - Else, if any of the determined causalities excluding Unknown is not Reportable No Value - Else, if all the determined causalities are blank.
18	Section Footer Text	It prints the configured text as specified in **Individual Report Common Line List** Configuration tab > **Section Footer** text below the event output table right after MedDRA J Version, in a new line. This text is repeated at the end of each **Clinical Compound Number** section.

#	Field Name	Description
19	Page Numbering	The page numbering for the Seiyakukyo report starts from 1 for each **Clinical Compound Number** section independently. The page numbering for Seiyakukyo report is printed in the middle of page footer in the following format: <current page number>/<Total Pages> The page numbering for attached CIOMS reports starts from 1 for each CIOMS independently. The page numbering for attached CIOMS reports is printed in the top left corner of CIOMS report table (same as in attached CIOMS in PSURs) in the following format: <current page number>/<Total Pages>
20	Page Size/Font	The MS Word A4 Landscape page size is used for Seiyakukyo report. **Ms Mincho** font is used for the report output.

4.2.8.5 CSV Output Format

The Seiyakukyo report also supports printing in the CSV format.

- The Seiyakukyo configuration data is not printed in the CSV format. Only the main Seiyakukyo report output is printed in CSV format.
- The Report Title is put as the first value in the first row.
- All the event rows from the report output including the Header row are put in separate rows.
- The MedDRA J version and Section Footer Text are put as separate rows at the end, in the same way as the report output.
- Each cell value for a row is put as individual item within that row in the CSV format.
- All the comma characters and new line characters within a cell value are supported and maintained in the CSV format. It must not break that cell value into multiple items in CSV. This is achieved by using double quote characters for the cell values to escape such characters.
- All the double quote characters within a cell value are replaced by 2 double-quote characters in the CSV format.
- All valid Japanese characters as specified for the **PMDA E2B** file (Main ESM J SRS > 19.6.1 point # 15 (c)) are supported by this CSV format.
- Different sections related to different case types and Clinical Compound Numbers are separated by a single blank line.

4.2.8.6 Periodic Report Process Flow

The Seiyakukyo Periodic report is handled in the same manner as other Japanese Periodic reports - PSR/ReSD and CSPSR. All the actions that are applicable to the existing Japanese reports are supported for Seiyakukyo Periodic reports as well.

- All the configured Seiyakukyo reports are listed on the **Periodic Report Configuration** page.

- All the actions supported on the **Periodic Report Configuration** page for CSPSR are supported for Seiyakukyo reports as well.
  - New Report
  - Copy
  - Modify
  - Delete
  - Print
- The **Print** dialog box for Seiyakukyo lists 2 output formats in the drop-down adjacent to the **Run Now** option - Word and CSV. The Word output format is selected by default.
  - Choosing the Word format for the **Run Now** action and clicking the **OK** button displays the output of the Seiyakukyo reports in Word format in the similar manner as CSPSR.
  - Choosing CSV format for **Run Now** action and clicking the **OK** button displays the Seiyakukyo reports in CSV format.
  - Irrespective of the format - Word or CSV, if the report is executed as **Final** or **Draft**, it is available in the same format through the standard - **FINAL** and **DRAFT** links in the row for that report on the **Periodic Report Library** screen. In case, you have executed the report with Internal and other options, it is available in the same format using the **DRAFT** link on the **Periodic Repot Library** screen.
  - No Watermark is put on the CSV format output. It is applicable only for the Word format output in the similar manner as CSPSR.
  - If a Submitted report is attempted to be printed in the CSV format, the application displays the following error message with the **OK** button:
    The report is already submitted. You cannot print this report again in CSV format.
    However, for Word format, it prints the Configuration page only without any error message.
- All the Seiyakukyo reports are also listed on the **Reports** > **Compliance** > **Periodic Reports** screen.
- All the actions supported on **Reports** > **Compliance** > **Periodic Reports** screen for CSPSR are supported for Seiyakukyo reports as well.
- The **View and Edit** Seiyakukyo dialog box (**View Report** right-click menu option) from **Reports** > **Compliance** > **Periodic Reports** screen, supports all the actions (in same manner as **View and Edit CSPSR** dialog box for CSPSR) for Seiyakukyo Word as well as CSV formats.
  - View
  - Check-in
  - Check-out
  - Publish
- The **View** or **Check-out** option displays the Seiyakukyo report in the same format (Word or CSV) that is chosen/checked-in by you.
- You are allowed to check-out the report in one format (CSV) and check-in the file in other format (WORD).

- If you click the **Publish** button and the last checked-in file is in the CSV format, it displays the following warning message with **Yes** and **No** buttons:
  As this report exists in CSV format, it will not be converted into PDF format while publishing it. It will be published as it is in CSV format itself. Do you want to proceed?

5

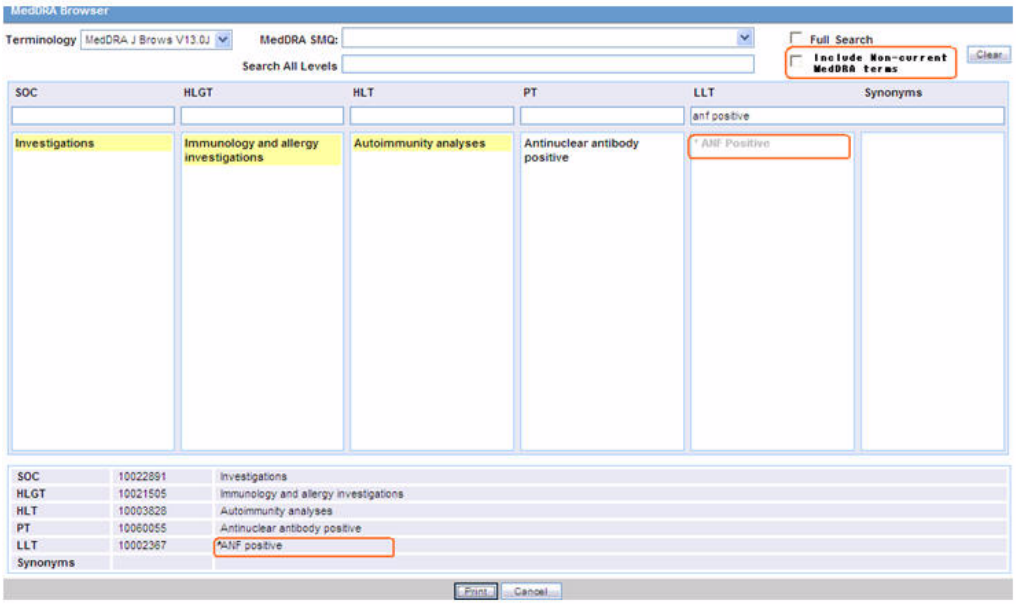
Utilities

This chapter lists the changes that have been introduced in MedDRA browser in the Argus Safety 7.0.3 release.

5.1 MedDRA Browser

- A new checkbox has been added in MedDRA browser "Include Non-current terms" as shown in the screenshot below. This is unchecked by default.

Figure 5–1 Case Form - MedDRA browser with Noncurrent terms option



- This checkbox is enabled only when MedDRA Browser is used for searching on local MedDRA dictionaries.
- When MedDRA Browser opens up to perform further searches on MedDRA Web Service, then this checkbox is unchecked and disabled.
- When the user searches for a term by marking "Include Non-current terms" checkbox, the system retrieves the matching non current terms along with the Current terms.
- The Non current LLT terms are displayed preceded with an asterisk (*) symbol separated by a space, in the search results grid as well as bottom section which displayed the selected term details. On clicking on non current term, system

displays its PT, HLT, HLGT, and SOC terms. Note that existing application logic to determine non-currency of a term is either based on English or Japanese currency of the term in different scenarios. Hence, the asterisk (*) symbol that is displayed is appropriate.

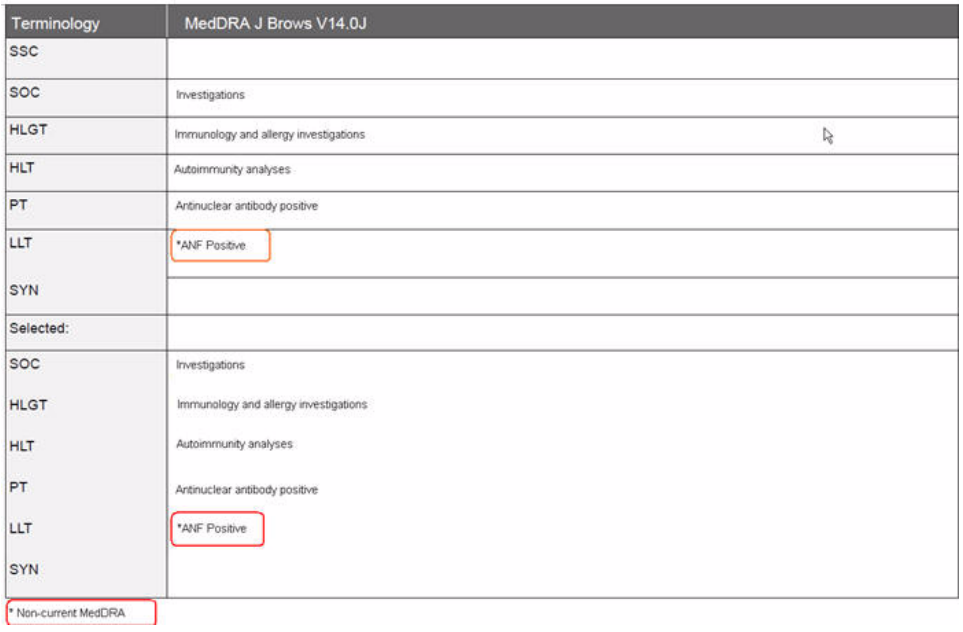
- If MedDRA J is not configured, then only English currency is used.
- If MedDRA J is configured and MedDRA Browser is opened from a Japanese base language screen, then only Japanese currency is used.
- If MedDRA J is configured, MedDRA Browser is opened from an English base language screen (for English as well as Argus J user), and Country of Incidence is Japan, then English as well as Japanese currency is used.
- If MedDRA J is configured, MedDRA Browser is opened from an English base language screen (for English as well as Argus J user), and Country of Incidence is not Japan, then only English currency is used.

- On selecting a noncurrent term in the MedDRA browser by clicking 'Select' button, the following message is displayed:

  Selected term is a non-current term in the MedDRA dictionary. Please select a current term.

- The MedDRA Browser print PDF also displays the asterisk (*) symbol in front of the non-current LLT.

Figure 5–2 Case Form - MedDRA browser Print



Terminology	MedDRA J Brows V14.0J
SSC	
SOC	Investigations
HLGT	Immunology and allergy investigations
HLT	Autoimmunity analyses
PT	Antinuclear antibody positive
LLT	*ANF Positive
SYN	
Selected:	
SOC	Investigations
HLGT	Immunology and allergy investigations
HLT	Autoimmunity analyses
PT	Antinuclear antibody positive
LLT	*ANF Positive
SYN	

* Non-current MedDRA

- The MedDRA Browser print PDF displays the footnote as follows in the Print PDF report:

  * Non-current MedDRA term